



Global Managing Cancer and Living Meaningfully (CALM) Knowledge Translation Program

Program Summary Document



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Contextualization of CALM

New medical treatments have been integrated into standard cancer care to great success. However, the benefits and integration of psychosocial care into palliative care and oncology is less common. Psychosocial care is a form of early palliative care. An evidence base has shown the benefits of incorporating palliative care early in the cancer journey. The purpose of the Global CALM Program is to create global partnerships in order to develop an evidence base for psychosocial and early palliative care in a systematic and unified manner, and to use it to advocate for the convergence of palliative and psychosocial care with oncology.

The Global CALM Program

The Global CALM Program is an international initiative to train clinicians in CALM therapy, to gather evidence about the implementation of CALM in diverse settings, and to make CALM available as part of standard cancer care for individuals facing metastatic or advanced cancer throughout the world. The program has developed an extensive network of sites internationally, who are committed to the implementation and research on CALM. **See Appendix A - Global CALM Site Leads**

CALM is a novel, brief, evidence-based, semi-structured psychotherapy that was developed by Drs. Gary Rodin and Sarah Hales at the Princess Margaret Cancer Centre to reduce distress and to promote the psychological well-being of advanced and metastatic cancer patients. CALM helps patients and their caregivers manage the practical and profound challenges associated with the disease and its treatment.

CALM therapy consists of three to six individual sessions delivered over three to six months by a wide range of specially trained healthcare professionals. Ultimately, CALM aims to help patients and caregivers:

- Manage the disease, symptoms and treatment, and communicate with healthcare providers.
- Adjust to changes in self-concept, personal relationships, and support needs.
- Find a sense of meaning and purpose in life.
- Prepare for the future, sustain hope, and face the end of life.

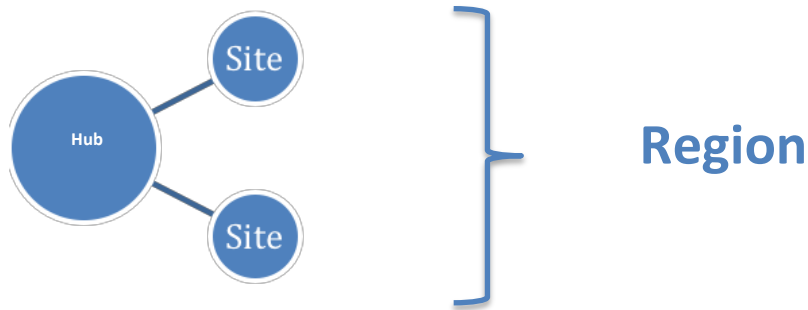
Global CALM Vision

The **vision** of the program is to reduce distress and promote the well-being of people facing metastatic or advanced cancer throughout the world. The **mission** is to make CALM a standard of care.

The program will achieve this by developing global partnerships to:

- **Build Global Capacity**

Global CALM sites will network and collaborate on research and clinical implementation to build a supportive network of hubs and regions. A **region** is defined as three or more sites, in close proximity, working together to advance CALM research and/or clinical implementation. At the centre of each region is a **hub**, which is defined as the leading site within the region.



- **Educate Providers**

The CALM team in Toronto will support sites by delivering bi-annual workshops in Toronto. GIPPEC will offer support to sites in hosting workshops in their home countries to educate staff in their centre and centres within their region.

Following training the site will be supported through online supervision with GIPPEC. To begin supervision, therapists at the sites must complete a training workshop and identify patient cases that can be discussed during supervision. A therapist is CALM certified when they have completed two successful cases under supervision. Trained therapists are encouraged to provide supervision with their site and to continue to connect with GIPPEC.

In the winter of 2019 the Global CALM team will launch an education platform to house training materials for sites to support learning prior to and after training. An education plan will be distributed in February 2019.

- **Advance Global Knowledge**

An objective of the Global Program is to continue to build an evidence base for CALM on an international scale through international exchange and collaboration on research. A data collection system for the gathering of real time patient level data to a centralized location has been developed. Further information on the data collection system can be found in the Data Collection System Section below.

CALM Certification

Collaborators can contribute to the Global CALM Program as a ‘Site and Research’ or ‘Research Study’ collaborator. Site and Research collaborators are committed to implementing CALM as a clinical program within their centres. Research Study collaborators are committed to conducting research on CALM in their centres. Certification for collaboration is outlined below.

Site and Research Certification

- At least three therapists committed to developing a CALM program within the site
- Dedicated CALM Site Lead
- Two therapists completed online supervision with GIPPEC



- Therapist lead to attend CALM workshop annually
- Commitment to share CALM data for research and program growth

Research Study Certification

- At least two therapists committed to research within site
- Therapists attended at least one CALM workshop
- Commitment to undergo online supervision with GIPPEC
- Commitment to identify funding to support site research
- Commitment to share CALM data for research and program growth

A Step-wise Approach to Implementation

Levels of implementation were developed to support sites with CALM implementation. In January 2018 all sites were assigned a level based on pre-defined criteria outlined in **Appendix B - Level of CALM Implementation**. The aim of sites is to progress through the levels of implementation with the goal of becoming a well-developed hub.

As new sites join the program, their level of implementation will be assessed using the Phase 1 Implementation forms.

<p>Level 1</p> <p>Entry Level</p> <p>Introductory training of therapist cohort, program development and site-specific adaptations.</p>	<p>Level 2</p> <p>Developing Hub</p> <p>Advanced therapist training and refinement of intervention delivery.</p>	<p>Level 3</p> <p>Well-Developed Hub</p> <p>Clinical program established, plus expansion to broaden clinical reach and to generate new knowledge through exploration or novel research questions.</p>	<p>Level 4</p> <p>Well-Developed Hub and Developing Region</p> <p>Development of a regional hub, which acts to build research, education and clinical capacity in other regional sites.</p>	<p>Level 5</p> <p>Well-Developed Hub and Well-Developed Region</p> <p>Regional hub of excellence established which acts as a leader in research, education and clinical capacity in the regional site.</p>
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A detailed list of criteria can be found in **Appendix B - Level of CALM Implementation**. The structure of the program is formatted such that each site leader is connected to a Global CALM Coordinator from GIPPEC. GIPPEC is available to support leaders in their programs as they progress through the levels.

To support progression sites will develop annual implementation plans with goals and objectives to progress through the levels of CALM. This process will be reviewed annually.



Metrics

The following metrics were agreed upon by the leadership group to track the implementation on CALM at the micro or project level:

Training	CALM Delivery	Quality	Impact
<ul style="list-style-type: none"> • # of workshop attendees • # of therapists completed supervision • # of therapists continuing to deliver CALM post supervision 	<ul style="list-style-type: none"> • # of completed cases <i>(include break down of men and prostate cancer patients)</i> • # of therapists delivering CALM • CALM clinic structure • # of completed new cases • <i>(include break down of men and prostate cancer patients)</i> • Programatic changes to support CALM 	<ul style="list-style-type: none"> • Treatment integrity • Workshop ratings • Supervision process 	<ul style="list-style-type: none"> • Patient outcomes • Therapist change • Impact on therapist • Pre-post change • RCT comparison • Grant funding dedicated to CALM

In addition to metrics to track growth and effectiveness of the project the following metrics will be tracked at the macro level or within the regional and health system levels of sites:

Site Level	Regional Level	Health System Level
<ul style="list-style-type: none"> • CALM clinic structure in place • CALM supervision structure in place • Programatic changes to support CALM • Pre-post change • RCT comparison • Grant funding dedicated to CALM 	<ul style="list-style-type: none"> • # of workshop attendees • # of therapist completed CALM supervision • # of completed new cases <i>(include break down of men and prostate cancer patients)</i> • # of completed cases <i>(include break down of men and prostate cancer patients)</i> • # of therapists delivering CALM post supervision • Workshop ratings • Patient outcomes • Therapist change • Impact on therapist 	<ul style="list-style-type: none"> • CALM assessment integrated into palliative care plan • CALM reflected as program within organization • Timely access to CALM intervention within system waittimes • Teaching and training provided to PSO disciplines and students • Implementation toolkit tailored to health system



Metrics will be collected at 6 months (December 2018), one year (June 2019), and annually thereafter. Documentation templates are included in **Appendix C - Scorecard** to track metrics over time.

Operationalizing CALM – Making it Happen

In the early stages of the program, leaders from the GIPPEC will provide support and resources to global sites to begin the process of developing hubs and regions. Toolkits have been developed and include:

- **International Workshop Toolkit:**

All sites are encouraged to host workshops in their sites and regions to continue to educate health care providers in CALM. Level 1 and 2 sites will receive support in offering international workshops hosted by CALM leaders (Drs. Gary Rodin and Sarah Hales). Workshops will be aimed at giving preliminary CALM training to therapists at each site. As sites progress the option to provide advanced CALM training is available. In order to support sites in hosting workshops, the Global CALM Team will provide a toolkit containing:

- CALM training videos and slides (subtitles in the language of the country can be added)
- Draft agenda
- Email package with publications and reference material for distribution to participants
- Standardized workshop evaluations
- Registrant list for tracking
- Sample budget

As sites progress the aim is for the site to build capacity to co-host shared workshops (at level 3 and 4 level), and eventually move towards independently providing workshops in their own region at level 5.

- **Research Toolkits**

A core component of the Global Program is to foster global research. GIPPEC will provide sites with a research toolkit to support and initiate the process of research at each site. The toolkit will have resources applicable to both site-localized and global CALM research, which includes:

- Templates for phase 1 protocol, consent forms, source notes
- Core measures
- Standardized process and support for the translation and back-translation of core measures for sites when the primary language is not English
- Data collection system instructions
- Sample project plan to support the organization with REB deadlines and study targets

GIPPEC will provide ongoing support for data analysis, write-up and publication throughout the development of research at each site as needed. As sites progress to levels 3-5 focus of research may become specific to each site. GIPPEC will provide support in reviewing and offering advice on protocols. Templates for sites will not be provided.



- **Supervision**

In the early phases (levels 1 and 2) the GIPPEC will support sites in supervision. Leaders (Drs. Gary Rodin and Sarah Hales) will supervise site leaders through two successful CALM cases. On a case by case basis leaders will begin to supervise therapists within their centres. GIPPEC’s aim is for each site to become self-sufficient in the supervision and training of CALM clinicians. GIPPEC will provide:

- Online group supervision for therapists’ first two successful CALM cases
- Treatment Integrity Rating Scale, to monitor the progress of therapist growth and determine readiness to supervise
- Package complete with documentation notes and templates
- Supervision Evaluation Questionnaire

CALM Research

GIPPEC is committed to supporting sites in the development, writing, analysis and publication of research. All sites are encouraged to publish on data collected at their sites. Patient reported outcomes and therapist outcomes will be collected.

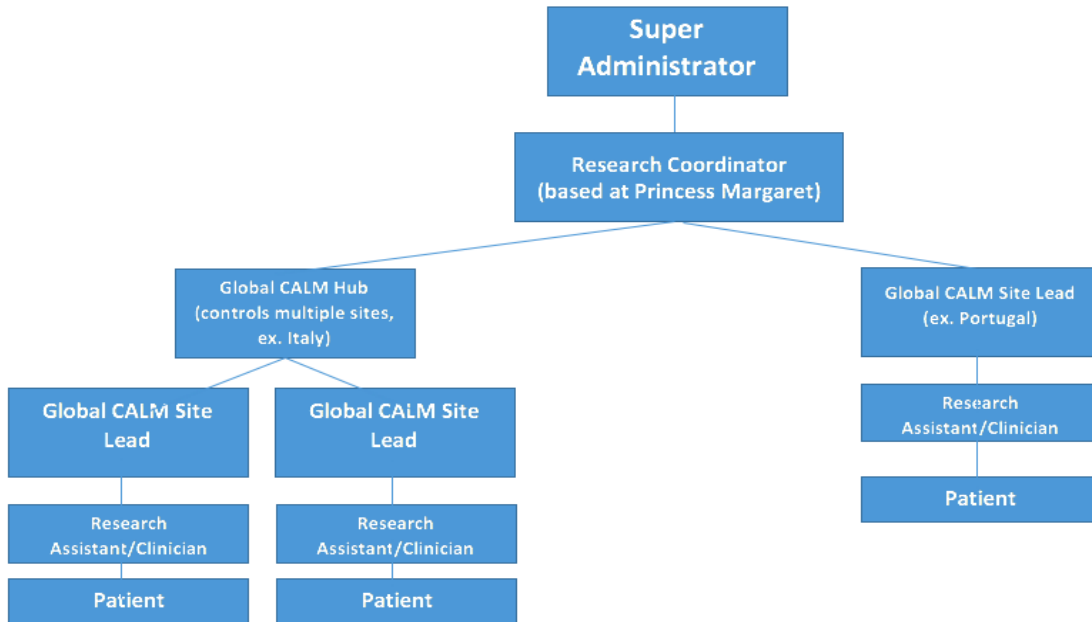
Patient reported outcomes vs. site and therapist outcomes

Patient Reported Outcomes	Site and Therapist Outcomes
<p>Outcome data demonstrates the effectiveness of CALM. Measures include:</p> <ul style="list-style-type: none"> • PH-Q9 • DADDS • ECR-M16 • QUAL-EC • CEQ-2 • Qualitative interviews with patients and/or caregivers (optional) 	<p>Site and therapist level data outline to what extent CALM is a standard of practice.</p> <ul style="list-style-type: none"> • Training (#of workshop attendees, # of therapists completed supervision, # of therapists continuing to deliver CALM post supervision) • CALM Delivery (# of completed cases, # of therapists delivering CALM, CALM clinic structure, # of completed new cases, programmatic changes) • Quality (treatment integrity, workshop ratings, supervision process) • Impact (patient outcomes, therapist change, impact on therapist (empathy), pre-post change, RCT comparison, funding dedicated to CALM)

The aim of the Global Program is to report on the implementation of CALM at a global level. Data will be reported on by the Global CALM Team in aggregate form on site and therapist level outcomes.

Data Collection System – Online System for Collaborative Research (OSCR)

The Online System for Collaborative Research (OSCR) is a secure and highly flexible system built to handle the privacy and logistical challenges of multi-centre clinical research. It provides a database and platform for each site to collect de-identified patient reported outcomes and therapist data on the implementation and feasibility of CALM at sites.



Participants at each site will be able to input their questionnaire responses directly into the system. Research clinicians and assistants will be able to access the data on the participants at their site. Access will be managed by GIPPEC and site leads. Each site lead will be provided view access and the ability to adapt data. The system is managed by the research coordinator at the centre and super administrator from GIPPEC. The aim of this system is to allow information to be collected on a global level while providing ease of access to users.

The front-end of the OSCR will be web-based and easily accessible from devices (i.e. smart phone, tablet, computer) through an internet browser. The system allows patients to directly input questionnaire responses. Answers are immediately encrypted and entered into the global database. Real-time data can be accessed by each site at any time and exported for external analysis. For security purposes, *all* actions within the system will be tracked and tied to a user's username.

Built-in to the OSCR are a number of analyses. It will be able to automatically score questionnaires and produce readily accessible visual representation of the scores at the individual level. Data stored in the system can be exported to for more detailed analyses, or for integration with on-site patient records.

Conclusion

The aim of the Global CALM Program is to build off the work described in this document to support and develop global CALM sites with the aim of improving access to psychosocial care and assessing the implementation of CALM in diverse settings.



Appendix A – Global CALM Site Leads



Australia: Peter MacCallum Cancer Centre
Maria Ftanou
Head of Clinical Psychology Department
Peter MacCallum Cancer Centre



Canada: BC Cancer Agency
Alan Bates
Provincial Practice Lead, Psychiatry
BC Cancer Agency



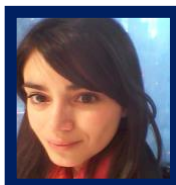
Canada: University of Calgary
Janet DeGroot
Psychiatrist, Psychodynamic Psychotherapist, and Associate Dean, Equity and Professionalism, University of Calgary, Department of Psychiatry



China: Peking University Cancer Hospital
Ying Pang
Clinical Psychologist
Peking University Cancer Hospital



China: University of Hong Kong
Wendy Lam
Associate Professor and Director of HKU Jockey Club Institute of Cancer



Chile: Instituto Oncológico Fundación Arturo López Pérez
Loreto Fernández
Clinical Psychologist
Instituto Oncológico Fundación Arturo López Pérez



Chile: National Cancer Institute in Santiago
Claudia Acevedo
Psychiatrist and Lead of PSO
National Cancer Institute in Santiago



Germany: University Medical Centre, Hamburg

Sigrun Vehling PhD

University Medical Center, Hamburg

Department of Medical Psychology, Palliative Care Unit, Medical Oncology



Germany: University Medical Centre, Leipzig

Anja Mehnert PhD

Head of Psychosocial Oncology, Department of Medical Psychology and Medical Sociology, University Medical Centre Leipzig



Italy: University of Ferrara

Rosangela Caruso

Assistant Professor in Psychiatry

University of Ferrara



Japan: National Cancer Centre

Ken Shimuzu

Chief Psychiatrist

National Cancer Center



Malaysia: National University of Malaysia

Caryn Mei Hsien Chan

Psychologist and Senior Lecturer

Faculty of Health Sciences at the National University of Malaysia



The Netherlands: Antoni van Leeuwenhoek Cancer Centre

Froukje De Vries MD PhD

Psychiatrist

Antoni van Leeuwenhoek, Amsterdam



The Netherlands: University of Groningen

Anne Reyners

Medical Oncologist

Faculty of Medical Science, University of Groningen



Portugal: Clinical Center of the Champalimaud Centre for the Unknown

Luzia Travado

Clinical Health Psychologist Specialized in PSO
Clinical Center of the Champalimaud Centre for the Unknown



South Korea: Kyungpook National University Hospital

Jungmin Woo

Psychiatrist
Kyungpook National University Hospital



United Kingdom: University College London

Sue Gessler PhD

Clinical Psychologist
University College London



United Kingdom: Kings College London and St. Christopher's Hospice

Christian Schulz-Quach MD, MSc

Visiting Lecturer in Palliative Care Psychiatry
Kings College London



United States: VCU Health and Massey Cancer Centre

Ashlee Loughan

Assistant Professor of Neurology and a Clinical Neuropsychologist
VCU Health and Massey Cancer Centre

Appendix B – Level of CALM Implementation



Level 1 Entry Level	Level 2 Developing Hub	Level 3 Well-Developed Hub	Level 4 Well-Developed Hub & Developing Region	Level 5 Well-Developed Hub & Well- Developed Region
Leadership, Training and Supervision				
<ul style="list-style-type: none"> Designated CALM leader(s) identified within site Leader(s) have attended CALM workshop Site committed to CALM, training therapist, and has developed plan implementation 	<ul style="list-style-type: none"> Leader(s) successfully completed 2 CALM cases under supervision with GIPPEC or other Level 5 centre Leader(s) fully trained in CALM Therapist cohort has received training 	<ul style="list-style-type: none"> Therapists undergoing supervision with site leader Leader(s) engaged with regular updates and discussion with GIPPEC or other level 5 site regarding therapist supervision Data collection part of usual care 	<ul style="list-style-type: none"> Leader(s) training and supervising CALM therapists with support from GIPPEC or level 5 site 	<ul style="list-style-type: none"> Leader(s) and CALM therapists fully trained Training/supervising other regions Supervision is self-sufficient within own site
Clinical Implementation				
<ul style="list-style-type: none"> Cohort of therapists (at least 2) identified to support clinical implementation 	<ul style="list-style-type: none"> Leader(s) seeing CALM patients 	<ul style="list-style-type: none"> Clinic structure forming to support CALM as usual care Leader(s) seeing patients as part of routine care Therapists begin seeing patients under supervision 	<ul style="list-style-type: none"> Clinic structure forming to support CALM as usual care Leader(s) seeing patients as part of routine care Cohort of therapists seeing CALM patients under supervision of site leader 	<ul style="list-style-type: none"> Functioning CALM clinic part of usual care Working within region to identify therapists in other sites to implement CALM
Research Progression (may vary depending on site research plans)				
<ul style="list-style-type: none"> Pilot and/or feasibility studies in progress 	<ul style="list-style-type: none"> Pilot and/or feasibility studies in progress 	<ul style="list-style-type: none"> Pilot and/or feasibility studies complete Plan for phase II studies 	<ul style="list-style-type: none"> Phase II studies or RCT 	<ul style="list-style-type: none"> Phase II studies or RCT



Item	Metric	December 2018	May 2019	Notes
<i>Project Level Metrics</i>				
Training				
1	Number of therapist who attended CALM workshop			
2	Number of therapists who have completed supervision			
3	Number of therapists delivering CALM post supervision			
CALM Delivery				
4	Number of completed CALM cases			
5	Number of therapists delivering CALM			
6	Is there a CALM clinic structure in place			
7	Number of completed new cases			
8	Have programmatic changes been implemented to support CALM (i.e. referral structure, other structures to support CALM, etc.)			
Quality				
9	Treatment integrity scores for therapists (report generated through OSCR)			
10	Workshop rating (if site hosted CALM workshop)			
11	Supervision process in place			
Impact				
12	Patient outcomes (report generated through OSCR)			
13	Therapist change over time (report generated through OSCR)			
14	Impact on therapist (report generated through OSCR)			
15	Pre-post change through research (if applicable)			
16	RCT comparison (if applicable)			
17	Grant funding dedicated to CALM			
<i>Health System Metrics</i>				
18	CALM assessment integrated into palliative care plan			
19	CALM reflected as program within organization			
20	Timely access to CALM intervention within health system wait times			
21	Teaching and training provided to PSO disciplines and students			
22	Implementation toolkit tailored to health care system			