SkIN Canada Priority Setting Initiative (PSI)

Protocol

List of Changes		
	Section	**Change**
1.	Introduction	Removed reference to schedule A (Tentative timeline)
2.	Identification of stakeholders	Removed CDF from list of organizations
3.	Survey 1	Removed section about providing preliminary list of skin conditions in survey 1
4.	Survey 1	Removed statement about participants selecting from list of options (only free-text submissions were possible)
5.	Survey 1	Changed criteria of submission/ranking – Removed available expertise
6.	Survey 1	Added "Synonyms and closely related conditions will be grouped together under a single condition category"
7.	Survey 1	Added SoGoSurvey as survey tool option
8.	Scoping Review	Updated search terms
9.	Scoping Review	Update search range to begin in 2011
10.	Survey 2	Removed paragraph about distinct patient/ caregiver survey
11.	Distill final list of knowledge gaps	Replaced Steering Committee with working groups
12.	Distill final list of knowledge gaps	Added Working Groups as one of the bodies to ensure answers to questions do not already exist
13.	Workshops	Changed the participation numbers
14.	Workshops	Removed the participated in two of the three surveys inclusion criteria
15.	Workshops	Added statement about JLA advisors
16.	Deliverables	Remove list of cross cutting themes

The Skin Investigation Network of Canada (SkIN Canada) is a newly established skin research network of interdisciplinary researchers, patients, clinicians, and other stakeholders. Funded by the Canadian Institutes of Health Research (CIHR), it was created to enhance and expand the national skin research landscape by promoting innovation and collaboration. The network is initially focusing on three topic areas deemed most relevant to the current skin research landscape in Canada, including (a) inflammatory skin conditions, (b) wound healing, skin fibrosis and regeneration (including burn injuries), and (c) skin cancer (other than melanoma).

The Priority Setting Initiative (PSI) is the natural first undertaking of SkIN Canada, intended to identify patient-relevant knowledge gaps and prioritize unanswered skin questions of concern to the Canadian population. This protocol sets the plan through which project objectives will be accomplished. The proposed methods are designed to conform with the James Lind Alliance's Guiding Principles of Priority Setting Exercises which includes[1]:

- Transparency of process, methods, and interests
- Audit trail of original submitted uncertainties, to final prioritised list
- Balanced inclusion of patient, carer and clinician interests and perspectives
- Exclusion of non-clinician researchers for voting purposes, although they may be involved and helpful in other aspects of the process
- Exclusion of groups/organizations that have significant competing or commercial interests, for example pharmaceutical companies
- Recognition that making priority decisions does not create new knowledge, but reviews evidence of uncertainty

The PSI results will be used to guide the inaugural activities of SkIN Canada and support the importance and funding of research aligned with the identified priorities. As SkIN Canada grows additional priority setting exercises will be conducted to identify potential areas of expansion.

Definitions

Healthcare topics that require additional investigation under the four CIHR pillars(biomedical science, clinical, health services, population health) and that are relevant to patients with skin conditions, will be referred to as patient relevant knowledge gaps. Research priorities refer to patient-relevant knowledge gaps that have been ranked by stakeholders according to their perceived importance.

Objectives

In collaboration with a diverse group of patients, caregivers, clinicians, and researchers:

- To prioritize and designate the top three skin conditions in each of the focus areas (inflammatory skin conditions; wound healing, fibrosis and regeneration; and skin cancer other than melanoma);
- To identify patient-relevant knowledge gaps in the designated skin conditions.
- To create, for each designated skin condition, a prioritized list of research questions of greatest importance to Canadians.
- To establish a process that can be used by skin research communities for conditions outside the designated skin conditions to further research in their respective area.

Governance

The SkIN Canada PSI is led and managed by the SkIN Canada Executive Committee. The Executive Committee is advised by a Steering Committee that provides operational and strategic recommendations. Members of both the Executive and the Steering committees represent a diversity of demographics, expertise, and interests in the Canadian skin research landscape.

Stakeholders:

- Patients who currently or previously live with skin conditions.
- Caregivers, defined as family and friends who provide support to people who live or lived with skin conditions
- Clinicians are healthcare providers involved in the diagnosis, management and treatment of skin conditions
- Skin researchers

Exclusions:

The SkIN Canada PSI surveys and workshops will be limited to people 16 years of age or older. Parents of individuals under 16 years of age are encouraged to participate as caregivers and consult with their children about shared concerns.

The SkIN Canada PSI is designed to determine the priorities of the Canadian stakeholders. As such, only individuals residing in Canada will be invited to complete the surveys and workshops.

Collection of personal data

Survey and workshop participants will provide identifying information (name, sex, race, age, home province, stakeholder role, contact info, skin-related topics of special interest) to confirm that they qualify as survey participants and to evaluate the diversity of respondents in terms of their geography, gender, and race. All responses will be kept confidential and accessible only by the SkIN Canada coordinator and Managing Director. Only aggregate data will be reported to prevent identification of specific respondents. Respondents will be given an option to join and receive future communication from SkIN Canada.

Priority setting protocol

We will use a seven-step process (Figure 1) adapted from priority setting protocols established by the James Lind Alliance[1] and the Council of Health Research for Development (COHRED)[2]. All stakeholders, including clinicians, researchers, patients, and caregivers, will be given the opportunity to provide input at various stages of the seven steps (Figure 1):

1. Identification of stakeholder organizations and the development of stakeholder outreach strategies.
2. Survey round 1 (clinicians and researchers) – determine designated skin conditions.

3. Scoping review of results from prior priority setting exercises for designated skin conditions.
4. Survey round 2 (patients, caregivers, clinicians, researchers) – identify patient-relevant knowledge gaps for designated skin conditions.
5. Distill a final exhaustive set of patient-relevant knowledge gaps.
6. Survey round 3 (patients, caregivers, clinicians) – ranking of priorities.
7. Workshops (patients, caregivers, clinicians) – discussion and finalized ranking of priorities.

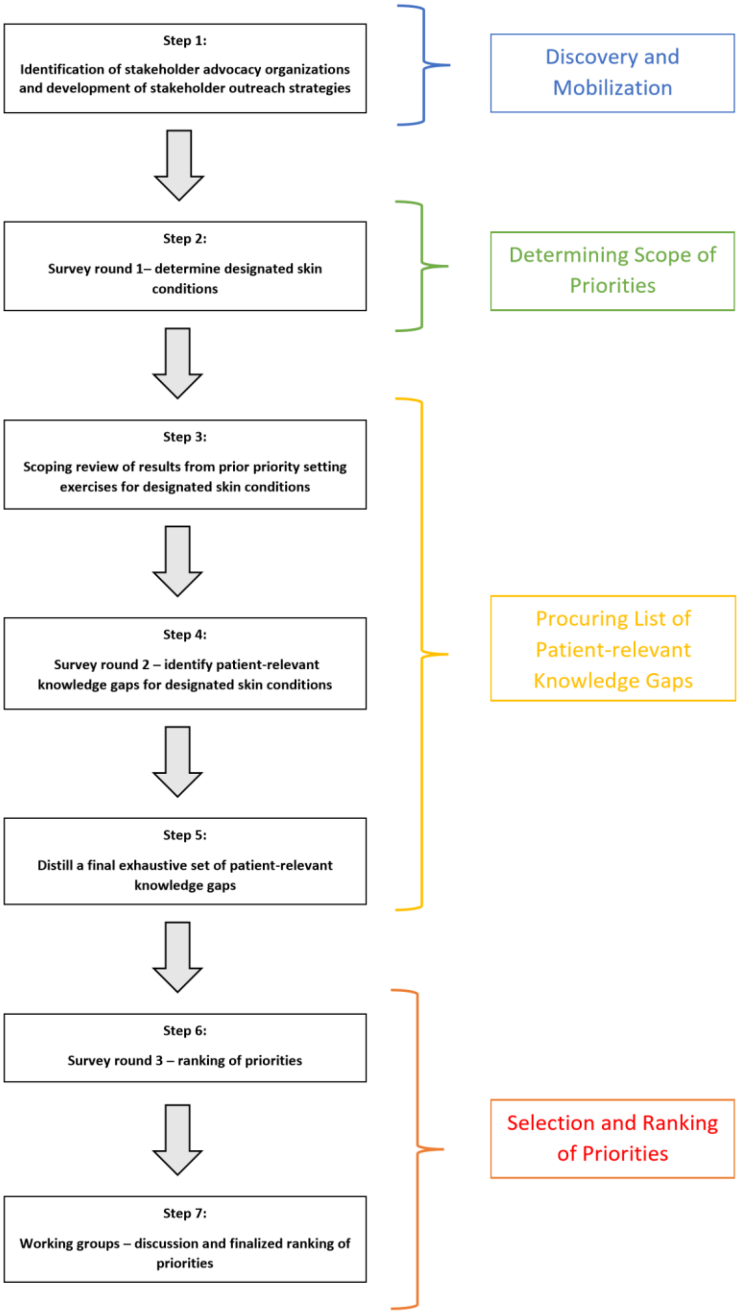

Fig. 1. Overview of Priority Setting Protocol

Step 1: Identification of stakeholder organizations and the development of stakeholder outreach strategies.

Stakeholder organizations will be identified through (a) existing professional networks of members of the Executive and Steering Committees, (b) web search of national organizations, and (c) personal knowledge of potential affiliated organizations. Potential partners will be contacted and informed of the establishment and aims of the SkIN Canada PSI, and will be asked to disseminate information about the project to their members and affiliates as well as participate in the recruitment of survey participants. These organizations include but are not limited to:

- Canadian Skin Patient Alliance (including all affiliate member organizations)
- Canadian Dermatology Association
- Skin Research Group of Canada
- Canadian Society of Investigative Dermatology
- Burn Care Canada
- University and hospital clinical divisions (Including all relevant specialties)

We will collaborate with stakeholder organizations to develop a promotion and survey distribution strategy. Methods may include mass email, website postings, and social media posts. While promotion strategies will be individually tailored to each organization based on their capabilities, all strategies should attempt to follow the survey and communication plan outlined in Figure 2. Each organization will email an invitation to its members to participate in the three survey rounds.

Surveys	Survey Duration	Phase	Timepoint	Communication methods
Survey Round 1	3 Weeks	Pre-Survey Communication	3 weeks prior to survey launch	All Available
		Survey Launch Communication	Day of Survey launch	All Available
		Mid-Survey Reminder	10 days after survey launch	Email
		End of Campaign Reminder	5 day before survey close	Email
Survey Round 2	3 Weeks	Survey Launch Communication	Day of Survey launch	All Available
		Mid-Survey Reminder	10 days after survey launch	Email
		End of Campaign Reminder	5 day before survey close	Email
Survey Round 3	4 Weeks	Survey Launch Communication	Day of Survey launch	All Available

		Mid-Survey Reminder	2 weeks after survey launch	Email
		End of Campaign Reminder	5 day before survey close	Email
Workshops	2 Weeks	Pre-Workshop Communication	3 weeks before first workshop	Email

Fig. 2. Survey and communication plan

In order to target only patient stakeholders who may be interested in participating in the PSI, patient organizations will be identified and approached after the completion of Survey Round 1, once the designated skin conditions have been determined.

Step 2: Survey round 1 (clinicians and researchers) – determine designated skin conditions

A survey designed to prioritize skin conditions within a Canadian skin research context will be distributed to clinicians and researchers by stakeholder organizations. To mitigate potential competing interests, patients and caregivers will be excluded from this survey round, as they may tend to prioritize conditions with which they have personal experience.

Participants will be invited to suggest the most important skin conditions based on a) their perceived burden and importance to Canadian patients (up to five per focus area) Participants will then be asked to rank their selections in order of importance.

An aggregate ranking will be created using the Ranked-Pairs (Tideman) electoral system. Ranked-Pairs is a form of Condorcet election method that ranks candidates based on voter preference in a series of head-to-head matchups. This ranking method was selected as it meets almost all formal voting criteria for fair and logical elections and produces a sorted list of candidates/priorities[5]. Synonyms and closely related conditions will be grouped together under a single condition category. The top three conditions from each focus area will be selected to proceed to the next step of priority setting.

The survey will be developed and administered online using REDCap or SoGoSurvey, with invitations distributed to potential respondents by organizations in conjunction with the communication plan (Figure 2). The survey is expected to remain open for three weeks, with an option for extension (at the discretion of the Executive Committee) should the response rate be deemed insufficient (target number for this step is at least 40 complete responses).

Step 3: Scoping review of results from prior skin-related priority setting exercises for designated skin conditions

We will perform a scoping literature review of previously conducted priority setting exercises for each designated skin condition in Step 2. We will search PubMed, Embase, and Google for English publications using the search terms:

(Priorit* OR Uncertaint* OR Gap* OR Research Question* OR Rank*) AND [Each designated skin condition determined in Survey Round 1]

To ensure they are relevant, we will only include priority setting exercises published since 2011. The priorities established by these previous exercises will be identified, screened for Canadian relevance, and recorded to a master list of existing priorities. The collected priorities will be summarised into a series of unranked patient-relevant knowledge gaps. Related priorities may be merged into a single knowledge gap. The master list will be categorized by area of focus and subcategorized into designated skin condition. An example of the master list summation and categorization can be seen in Appendix B.

Step 4: Survey round 2 (patients, caregivers, clinicians, researchers) – identify patient-relevant knowledge gaps for designated skin conditions

This survey will capture the unanswered questions that patients, caregivers, clinicians, and researchers have on the cause, prevention, diagnosis, treatment, and care of the designated skin conditions.

All stakeholders will be provided the lists of existing knowledge gaps for the designated skin conditions they selected. They will be asked to add up to tenresearch questions they believe are missing in the existing lists. The researcher/clinician survey will possess one additional item that requests suggestions for possible cross-cutting priorities that can be applied to multiple designated skin conditions or research areas of focus.

The survey will be administered online for three weeks, with an option for extension (at the discretion of the Executive Committee) should the rate of response be deemed insufficient (target number for this step is at least 40 complete responses).

Step 5: Distill a final exhaustive set of patient-relevant knowledge gaps

The results of Survey Round 2 will be a collection of uncurated questions and comments. This collection of raw entries will be categorized and refined under the oversight of the SkIN Canada Working Groups. The submissions will be summarized into clear, simplified patient-relevant knowledge gaps, combining duplicates and removing items that are out of scope. The knowledge gaps produced in the processes will be checked by the Executive Committee and Working Groups against the current peer-reviewed literature to ensure a consensus answer does not already exist. Potential cross-cutting themes will also be identified during this review process. The knowledge gaps determined to be unanswered will be collated into nine unranked long lists of patient-relevant knowledge gaps, corresponding to the three designated skin conditions selected from each focus area.

Step 6: Survey round 3 (patients, caregivers, clinicians) – ranking of priorities

The results of Step 5 will be distributed to patients, caregivers, and clinicians who participated in Survey Rounds 1 or 2. To mitigate potential competing interests, researchers will be excluded from this survey round, as they may tend to prioritize knowledge gaps that reflect their expertise and field of research. Those who participate in Survey Round 3 will be ineligible to apply as principal investigator for research grants from SkIN Canada for the next 3 years.

These participants will be asked which of the nine designated skin conditions are relevant to them; they will then be administered the corresponding long lists. For each list they have access to, participants will be asked to select and rank the 10 knowledge gaps they deem most important. The result will be aggregated using the Ranked-Pair (Tideman) electoral system, and the top 20 priorities from each list will be shortlisted.

The survey will be administered online for four weeks, with an option for extension (at the discretion of the Executive Committee) should the rate of response be deemed insufficient (target number for this step is at least 40 complete responses).

Step 7: Workshops (patients, caregivers, clinicians) – discussion and finalized ranking of priorities

The final stage will consist of a virtual workshop for each skin condition of interest. Each workshop will comprise of four to eight patients or caregivers, who will be compensated for their time, and four to eight clinicians. Those who participate in a workshop will be ineligible to apply as principal investigator for research grants from SkIN Canada for the next 3 years.

Workshops will be facilitated by James Lind Alliance certified advisors. Using the workshop framework outlined in Appendix C, the shortlists will be re-prioritized. The top ten priorities in each category will constitute the final list of priorities for that designated skin condition. The bottom ten priorities will be defined as notable questions.

Deliverables

We will produce the top ten lists of priorities for the nine designated skin conditions of interest. These will be adopted as the official priorities of SkIN Canada, guiding its scope of activities and funding opportunities. A report of the results will be available on the SkIN Canada public website and distributed to relevant organizations and stakeholders. This report will outline the finalized shortlists of priorities and respondent characteristics. A manuscript for each focus area describing the results of the prioritization process will be submitted for publication.