Development and Validation of a Canine Health Related QoL Questionnaire and a Human-Canine Bond Questionnaire for Use in Veterinary Practice

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Article

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Abstract: Background: Valid questionnaires to assess dogs' health-related quality of life (HRQoL) in veterinary practice can improve canine health outcomes and communications between veterinarians and dog caretakers. The Canine HRQoL Questionnaire (HRQoL-Q) and the Human-Canine Bond Questionnaire (HCBQ) were developed and validated to fulfill this need. **Methods:** A literature review, interviews with veterinarians, and focus groups with caretakers were conducted to generate questionnaire items to develop draft questionnaires, piloted with caretakers to establish content validity. Measurement properties were evaluated using data from a prospective survey study (N = 327). **Results:** Draft Canine HRQoL-Q and HCBQ measures were developed, including a domain structure, items, recall period, and scale/response options. Refinements were made via iterative cognitive interviews with caretakers. When no additional revisions were indicated and content validity established, the questionnaires were psychometrically tested. Ceiling effects were observed for all items, and factor analyses indicated that pre-specified domains are appropriate. Internal consistency was demonstrated for the HCBQ (α = 0.79–0.86) and all but the canine HRQoL-Q social functioning domain (α = 0.60)). Test-retest reliability for the canine HRQoL-Q was generally moderate-to-good (intraclass correlation coefficients [ICCs] > 0.79). Test-retest reliability for the HCBQ was moderate (ICCs: 0.70–0.79), except the trust domain (ICC: 0.58). Known-groups validity was demonstrated by significant differences ($p < 0.05$) in scores by health/bonding groups. Convergent validity was supported (r > 0.40) between all domains and the total score for both questionnaires. **Conclusions:** The Canine HRQoL-Q and the HCBQ are valid, reliable measures of canine HRQoL for use in veterinary clinics and appear to measure related but distinct concepts that contribute to canine health and wellness.

Keywords: canine; health-related quality of life; human-canine bond; validity; reliability; outcomes

1. Introduction

Health-related quality of life (HRQOL) is a multi-dimensional concept that includes domains related to physical, mental/cognitive, emotional, and social functioning, and focuses on the impact health status has on quality of life. HRQoL measures can be either generic or disease-specific. A generic HRQoL measure consists of general health-related items to assess the general health status and well-being of healthy dogs as well as dogs with chronic illness. Disease-specific HRQoL measures include items specifically related to a disease state and are designed to be more sensitive to change in assessing that disease state. HRQoL measures are increasingly used in human medicine in clinical trials to assess efficacy and safety of new medicines and in clinical care to track patients' health status over time, encourage discussions between health care providers and patients, and support better health outcomes.

Development and use of HRQoL measures in human health for use in drug approval and clinical care has gained the support of regulatory agencies. The FDA guidance to the pharmaceutical industry on the development of valid and reliable outcomes measures for use in human studies (2009)

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emphasizes the importance of qualitative research to develop questionnaires that measure what is most important to patients in a population of interest, and quantitative research to evaluate the instrument's measurement properties [1]. More recently, the development of four Patient-Focused Drug Development guidance documents by FDA is underway to guide stakeholders on the collection and submission of patient experience data via HRQoL measures [2].

While the overall, general health status of companion animals is the central focus of routine visits to the veterinary clinic, the availability of generic, valid and reliable HRQoL measures, developed to the standards required in human medicine, to determine health status and track progression over time are limited. At the same time, recognition is growing that HRQoL measures to foster communications between caretakers and their veterinarians guide decisions on routine care in clinical practice, and monitor pet HRQoL over time is a key unmet need [3–6]. In human medicine, evidence demonstrating that clinicians miss about half of their patients' symptoms during treatment which has led to growing interest in integrating measures of HRQoL in routine clinical practice [7]. The downstream consequences of missing symptoms include patient suffering due to poor symptom control, missed treatments, emergency department visits and hospitalizations, and physical debility [8]. Studies have shown that systematic monitoring of patients' symptoms using HRQoL measures closes this gap, improving patient-clinician communication, clinician awareness of symptoms, symptom management, patient satisfaction, quality of life, and overall survival [9].

To date, most measures of canine HRQoL have been developed and utilized primarily to assess impacts of specific conditions such as cancer and dermatitis, or related concepts such as pain and pruritus [10,11]. While some generic measures of canine HRQoL do exist [12–14], they do not appear to follow all of the principles or best research practices in the regulatory guidance documents for the development of valid and reliable HRQoL measures. In particular, the guidances stress the need for qualitative research with the target population (dog caretakers) who will be completing the measure to understand and identify the concepts related to the dog's HRQoL that they perceive are important to measure. Items for the measure should be generated based on this understanding, using the language of the target population. Once the items are generated and a draft questionnaire is developed, the guidances support piloting the measures via cognitive interviews with additional caretakers to revise the questionnaires and establish the content validity, qualitatively, prior to quantitative testing [1,2].

According to the American Veterinary Medicine Association, "the human-animal bond is a mutually beneficial and dynamic relationship between people and animals that is influenced by behaviors essential to the health and wellbeing of both". [15]. There is recognition that a dog's HRQoL is impacted by the bond between caretaker and canine that is dependent on their relationship to each other and that contributes to the HRQoL of both the canine and caretaker [16]. However, none of the existing canine HRQoL measures include an assessment of this aspect of canine HRQoL. Thus, development of a valid and reliable measure to assess the relationship between caretaker and dog or human-canine bond (HCB) could provide a more comprehensive, holistic understanding of canine HRQoL.

The current project was undertaken to fill the need for comprehensive, holistic measures based on concepts important to dog caretakers and veterinarians. The development and validation of two new, related outcomes measures, the Canine HRQoL Questionnaire (Canine HRQoL-Q) and the Human Canine Bond Questionnaire (HCBQ), developed in accordance with the principles outlined in the 2009 FDA guidance, are reported here.

2. Materials and Methods

The Canine HRQoL-Q and HCBQ were developed in two parts using a mixed methods approach. The first part of development included a targeted literature review and qualitative concept elicitation interviews with veterinarians and dog caretakers to identify concepts perceived as important to include in questionnaires to assess canine HRQoL and the HCB. Results from the literature review and interviews were used for the development of items, reflective of the descriptions and language used by caretakers, and to define a domain structure for the questionnaires. In addition

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to the items, a recall period (time that should be considered when responding to items), and a scale were chosen that were appropriate for the items leading to the development of the two draft questionnaires, the Canine HRQoL-Q and the HCBQ.

Once the draft questionnaires were developed, cognitive interviews with a separate group of dog caretakers were conducted to establish content validity of the questionnaires and to refine the questionnaires for quantitative psychometric testing. To establish content validity, (1) the items in the questionnaire should have a single concept or express a single idea to caretakers, be unambiguous, easily comprehended by the target audience; (2) there should be no important missing concepts; (3) the instructions for completion and recall period (period of time a respondent is asked to consider when completing a measure) should be understood and appropriate; (4) it should be easy for respondents to choose a response to each item (the scale, number and type of response options are appropriate for the items) [17].

Interviews were conducted iteratively to allow the research team to evaluate results and make indicated revisions as the interviews progressed. Interviews were conducted until no additional revisions were indicated.

The second part of the study focused on a quantitative assessment of the psychometric properties of the canine HRQoL-Q and the HCBQ (i.e., validation of the measure). Measurement properties assessed included item-level analyses, tests of reliability (internal consistency and test-retest), and an assessment of validity (factor structure, known-groups validity, convergent validity).

2.1. Part 1: Questionnaire Development and Content Validation

2.1.1. Concept Elicitation, Item Generation, Draft Questionnaire Development

Concept elicitation to identify concepts important to canine HRQoL and the HCB was undertaken with 20 English-speaking dog caregivers in the US who cared for a diverse population of dogs with respect to age, size, breed, and varying health status. The participants were included if they were caregivers of the dog for at least six months. Dog caregivers were excluded if they fostered a dog as they may not have known as much about the dog's HRQoL or may not have bonded with a dog similarly to an owner. The participants were sampled from ICON plc employees located at various locations across the US between February and March of 2021. Four virtual focus groups with approximately five participants each (20 total) lasting up to 120 min were conducted in English via a WebEx video-enabled platform. ICON employees were purposively selected to obtain as diverse a population of participants with respect to gender, age, ethnicity, geographic location, and breed/health status of dogs as possible.

Participants were required to create photo collages prior to joining the focus groups. Photo collages are a projective technique in which participants project their opinions and beliefs onto images that they select about a particular topic. This allows participants to articulate their thoughts and experiences at a subconscious level that is difficult to reach with direct questioning techniques frequently used in qualitative interviewing. For the focus groups, the participants were asked to choose several photos and write a brief description to explain why they chose each photo to create two photo collages, one collage depicting concepts they perceived as important to a dog's HRQoL and a second collage for the HCB. During the focus groups, the participants elaborated on these concepts, explaining why they selected each image, which enabled them to articulate and expand on how and why they perceived the concepts elicited via the photos were important to them. The order of discussion of the HRQoL and HCB collages was counterbalanced from group to group.

The participants were also asked to complete the published 15-item canine HRQoL survey (CHQLS-15) and to provide perspective on the relevance and importance of the concepts addressed in the questionnaire. In addition, participants reviewed and discussed 10–15 HCB concepts that were developed from a review of the literature and veterinarian interviews and emailed to them prior to the focus group. They were asked to rate the concepts by ranking them "important", "maybe/maybe not important", and "not important" based on how relevant each item was to their relationship with

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their dog(s). Items chosen by participants as the most relevant were reviewed and discussed further. The order of discussion of the HRQoL and HCB concepts was counterbalanced from group to group.

The results of the concept elicitation focus groups, literature review, and interviews with veterinarians informed item generation for the draft questionnaires. General considerations for item generation included: each item should contain a single concept, should be unambiguous and clearly stated in language understood by the respondent, and should contain concepts important or relevant to respondents. Other elements of the questionnaire that were carefully considered included the instructions for completing the questionnaires, the recall period and scale (i.e., number of response options and type of scale, e.g., frequency, agreement, severity).

2.1.2. Pilot Testing/Cognitive Interviews

Following development of the first draft of the questionnaires, cognitive interviews were conducted with a new group of dog caregivers to assess content validity of the questionnaires, including comprehension, interpretation, and relevance of each item, ease of completion and understanding of the instructions for both questionnaires, utility of the scale and appropriateness of the type and number of response options in the scale, and missing concepts.

Individual cognitive interviews were conducted with 16 English-speaking dog caregivers in the US. Similarly to the concept elicitation focus groups, caregivers were included if they cared for the dog for at least six months. Caregivers were excluded if they fostered a dog as they may not have known as much about the dog's HRQoL or may not have bonded with a dog similarly to an owner. Interviews were conducted virtually using a video-enabled WebEx platform. Participants were recruited by the Schlesinger Group, a third-party recruitment agency, for interviews conducted in July 2021.

During the cognitive interviews, participants were asked to complete the draft questionnaires and, by way of semi-structured questions, to explain how they interpreted items and how they arrived at their answers. They were asked to complete the questionnaire and then were asked questions regarding ease of completion and understanding of the instructions for both questionnaires, relevancy and appropriateness of the recall period, their interpretation and perceived relevance of each item, interpretability and suitability of response options or scale, ease of responding or choosing between response options, the number and type of response options, and any missing items or concepts that should be included. The order of completion and discussion of HRQoL and HCB questionnaires was counterbalanced. The questionnaires were refined, based on responses from participants, and the questionnaires were finalized for psychometric testing.

2.2. Part 2: Psychometric Validation

Study Population

The psychometric validation of the canine HRQoL-Q and the HCBQ developed from the first part of the study was undertaken using data from a non-interventional, prospective survey with a 2-week follow-up among canine caregivers who provide at least 50% of a dog's care (N = 327). Participants included caregivers of dogs for at least six months who were at least 18 years of age, English-speaking, located in the U.S and able to provide consent to participate in the study. Dogs were excluded from the study if they were fostered. Data were collected using online surveys. Interested participants received an email link to determine eligibility. If participants met the eligibility criteria, they were able to review the study information sheet and consent to participate in the study. Following screening and informed consent, participants were asked to complete a sociodemographic form, and were redirected to the survey (which included the canine HRQoL-Q, the HCBQ. An Owner's Global Impression of Health (OGIH; i.e., a single-item measure that assesses a caregiver's impression of their dog's general health as "excellent", "very good", "good", "fair", and "poor") was also assessed. Participants who were followed-up were only required to complete the questionnaires at the second time point/visit.

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2.3. Statistical Analysis

Analyses were performed under a pre-specified statistical analysis plan. SAS version 9.4 (SAS Institute, Cary, NC) was used for all statistical analyses. The analysis of the psychometric properties of the canine HRQoL-Q and the HCBQ were conducted using data from all caregivers included in the psychometric study dataset. The electronic collection system required completion of each item by the respondent to proceed through the instrument; as such, no skipping of items was permitted and no missing values were expected. If a respondent did not complete the questionnaire, responses were not used. Missing scores on the OGIH were not imputed for the psychometric validation, as this is a single-item measure.

2.3.1. Item-Level Analyses

Item-level analyses were evaluated using visit 1 data and included use of response categories for each item (i.e., frequency and percentage of participants in each response category), measures of central tendency (to assess the distribution of total and domain scores), and an assessment of floor and ceiling effects [18].

2.3.2. Factor Structure

A confirmatory factor analysis (CFA) was performed at visit 1 to evaluate the factor structure of the canine HRQoL-Q and the HCBQ, as the measures were developed with pre-specified domains. Maximum likelihood estimator with robust standard errors were used to identify the factor solution, with the following fit statistics computed: Comparative Fit Index (CFI), Root-Mean Square Error of Approximation (RMSEA) with 95% confidence interval (CI), and Standardized Root Mean Squared Residual (SRMR).

2.3.3. Reliability

Internal consistency reliability was evaluated at visit 1 using the Cronbach's alpha coefficient, with a target value of 0.7 indicating good internal consistency, and using item-total correlations, with a significant correlation > 0.30 showing good homogeneity [19–21].

Test-retest reliability was assessed between visits 1 and 2 among dogs whose owners reported no change on the OGIH (i.e., stable dogs). Mean differences were calculated to compare canine HRQoL-Q and HCBQ total and domain scores between the two assessment visits. The intraclass correlation coefficient (ICC) with 95% confidence intervals was computed where ≥0.7 (absolute ICC and lower 95% confidence interval limit) indicates good reproducibility [22–24].

2.3.4. Validity

Known-groups validity was examined at visit 1 to determine whether the canine HRQoL-Q and HCBQ can distinguish between groups with expected differences in scores. For the canine HRQoL-Q, groups were defined using (1) canine health/disease state (healthy, non-food allergy/skin problem, ear infection); (2) OGIH groups (excellent, very good, good, fair/poor); and (3) general health/HRQoL item tertiles (items 8a and 8b). For the HCBQ, groups were defined using (1) canine health/disease state (healthy, non-food allergy/skin problem, ear infection); (2) OGIH groups (excellent, very good, good, fair/poor); and (3) general bonding item tertiles (items 4a and 4b), although the former categories may not work as well for bonding. Using analysis of variance (ANOVA) models, differences in total and domain scores for both questionnaires were assessed by severity groups. Although the questionnaires are intended to be used with healthy dogs, recruitment for this study included dogs with variable health statuses as reported by their caregivers, e.g., those that are considered healthy by their caregivers as well as dogs that are reported to be unwell (specifically those with atopy and ear infections) to assess this psychometric property.

Given that no other measures were included in the study, convergent validity was assessed by examining correlations between all total and domain scores for the canine HRQoL questionnaire and HCBQ, separately (i.e., using a domain-domain type matrix) at visit 1. Stronger correlations were

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expected where a larger overlap of concepts was evident, thus suggesting that the tools measure as intended. Further, the canine HRQoL-Q and HCBQ total scores were correlated with each other (using Pearson correlations) to test whether the HCB is associated with canine HRQoL.

3. Ethical Considerations

Ethical approval was obtained from Salus IRB, a central Ethics Committees for both Part 1 and 2 of the study.

4. Results

4.1. Part 1: Qualitative Development of Draft Versions of the Canine HRQoL-Q and HCBQ

4.1.1. Development of Initial Drafts of the Canine HRQoL and HCB Questionnaires

The baseline characteristics of the participants included in the focus groups are presented in Supplemental Table S1. Participants were predominantly White (80%) and female (80%) with a mean age of 45 years. Their dogs were diverse with respect to age, breed, size, and health status. The mean age of the dogs was 7.3 years (see Supplemental Table S2). The highest proportion of participants reported owning their dog for between 1–5 years (44%) and between 5–10 years (32%). Most caregivers reported visiting the vet for their dogs every 3–6 months (24%), twice per year (20%), and once per year (36%). Dog breeds varied and included a number of mixed breeds (e.g., Schnoodle, Goldendoodle, Pomeranian-Chihuahua, Yorkshire Terrier mix and Poodle mix). No participants reported their dog was a service dog; however, some dogs received therapy dog training (4%), citizen training (4%) (i.e., training involving the teaching of good manners and responsible ownership of dogs), or training as an emotional support animal (4%). Finally, most dogs were reported to be generally healthy (68%).

The HRQoL concepts identified for inclusion in the draft Canine HRQoL-Q included: healthy weight, mobility, exercise, spending time with the family, everyday/frequency stimulation, mood, health indicators, food and water, poor appetite, age-related issues, training, mental status, and separation. From the collage, HRQoL discussion, and the completion of the CHQLS-15, concepts important to caretakers were identified and grouped into domains or themes and items reflective of the concepts and language used by caretakers were generated for the development of the draft Canine HRQoL-Q.

The draft Canine HRQoL-Q consisted of 36-items organized into eight domains or themes: mobility, energy & vitality, physical health, appetite and hydration, emotional functioning, cognitive functioning, social functioning, and general health. Each of the items is rated on a 5-point Likert Scale as follows: 1 = strongly disagree; 2 = disagree 3 = neither agree nor disagree; 4 = agree; and 5 = strongly agree. The general health domain includes two global concept items which assess canine overall health and HRQoL, respectively, on a scale ranging from 0 (very poor) to 10 (excellent). Higher scores denote better canine HRQoL. Caretakers were asked to consider the items at the present time, in their current state.

During the HCB rating exercise, participants rated several concepts as most important, including meeting the dog's needs (n = 15) (e.g., basic needs, enrichment needs, social needs), caring for and protecting the dog (n = 14), the dog is a friend or companion (n = 14), the dog is a family member (n = 12), the dog is a priority in the caregiver's life (n = 12), including the dog in activities (n = 11) (e.g., hiking, walking), recognizing the dog's emotions (n = 11), emotional benefits of dog caregiving (n = 10) (e.g., raised self-esteem), caregiver as the leader (n = 10), caring for the dog in their old age (n = 15), caring for an unhealthy dog (n = 14), and cost of caring for the dog (n = 10). The latter three concepts were end-of-life considerations and, thus, not included in the draft questionnaire. The concept of dogs caring for and protecting the caregiver was rated with medium importance (n = 12). Based on these findings, the following domains or themes were identified: trust, communication, spending quality time/companionship, and security/comfort.

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Based on the results from the focus groups, a draft HCBQ was developed as a 21-item measure that evaluates the human-canine relationship from the caregiver and dog's perspectives across four domains (trust & security, communication, spending quality time/companionship, and general bonding). Similar to the canine HRQoL-Q, each item assesses the degree to which the caregiver agrees or disagrees with statements regarding their relationship with their canine on a 5-point Likert scale (1–5, with 1 = strongly disagree to 5 = strongly agree). The general bonding domain includes two global concept items which assess the strength of the caregiver's bond to the dog and attachment of the caregiver to the dog on a scale of 1 (not strong/attached at all) to 10 (as strong/attached as I could imagine). Higher scores indicate a higher (stronger) human-canine bond.

4.1.2. Assessing Content Validity and Refining Questionnaires via Cognitive Interviews

The baseline characteristics of the participants included in cognitive interviews are presented in Supplemental Table S3. Participants were predominantly female (56%) with a mean age of 49 years. Half of the participants were White (50%) and approximately one-third were either married (38%) or single (31%). Most participants worked either full-time (56%) or part-time (17%). Regarding education level, 25% had completed some college education without a degree, 13% had a two-year Associate's degree, 31% had a four-year Bachelor's degree, 24% had a Master's degree, and 6% had a doctoral or professional degree. Most participants earned incomes in the $30,000–$59,999 (31%) and $60,000–$89,999 (31%) ranges. Lastly, the majority of participants (69%) did not have children in the household.

After completing each of the questionnaires, participant comments and thoughts about the questionnaires were carefully reviewed and used to guide revisions to the draft questionnaires. Specifically, participants provided information on the wording, clarity, and relevancy of the items, the recall period, response options and scale, and instructions that was used to edit each element of the questionnaires.

Based on comments from caretakers, a number of items were removed from the HRQoL-Q due to: a lack of relevance (e.g., "My dog liked to meet other people/dogs he/she does not know" was irrelevant as participants reported that their dogs did not like strange dogs or people); lack of universality (e.g., "My dog had difficulty climbing stairs" was not applicable to all dogs as some caregivers did not have stairs); multiple interpretations or meanings of some concepts (e.g., "My dog preferred to be alone" could be due to other factors such as the dog's mood or the weather); overlapping or redundant items (e.g., "My dog played" and "My dog was interested in play"); lack of clarity or comprehension (e.g., "frisk", "pep", "boundless energy", "patchy coat", "clear eyes", and "easily confused"); confusion between similar items (e.g., "hair loss" and "shedding"); and, inapplicability of concepts to a dog (e.g., it was unclear what "easy-going" means for a dog).

Items in the HRQoL-Q were reworded due to: inconsistent tense and phrasing (e.g., "My dog has no difficulty walking" changed to "My dog has difficulty walking"); problematic item interpretation (e.g., the interpretation of "stiff" leading to a change from "My dog's movements were stiff" to "My dog has been limping"); breed-dependent concepts (e.g., "My dog was energetic" changed to "My dog's energy level was the same as usual" as some breeds are not energetic); overlap of concepts (e.g., "remembered where things were", "was forgetful", and "got lost somewhere that should have been familiar"); and lack of clarity or parsimony (e.g., "My dog did not recognize people or situations that should have been familiar to him/her" changed to "My dog seems to be forgetting people or places").

Regarding the HCBQ, items were removed due to: lack of relevance (e.g., "My dog's daily behavior is predictable" in the communication domain was irrelevant as unpredictable behavior did not impact communication); social desirability bias (e.g., "Trust is important for a good relationship with my dog"); inability to measure the concept (e.g., participant could not tell if their "dog knows [they] really care about him/her"); reflection of the caregiver (e.g., "I think my dog knows I really care about him/her" could be a reflection of the caregiver); overlap with other concepts (e.g., "My dog is soothed by my presence" overlaps with "My dog is comforted by my presence"); problematic item interpretation (e.g., "mental stimulation", following owner "guidance"); preference of one concept

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over another (e.g., "companion" versus "inseparable"); and context of future administration of the questionnaire (e.g., "My dog would rather be with me than anyone else" does not fit the context of future administration as the person bringing the dog to the vet/completing the questionnaire is not necessarily the dog's favorite person).

Based on comments from caretakers, some items in the HCBQ were reworded due to: relevancy of a concept (e.g., "My dog checks in on me throughout the day" changed to "My dog checks in on me routinely when we are together" as some people are not home throughout the day); inappropriate or awkward terminology (e.g., "My dog wants to make me proud of him/her" changed to "My dog seeks my approval"); and suggestions for more generally relevant phrasing (e.g., "My dog and I enjoy exercising together" changed to "My dog and I enjoy physical activities together" since not all caretakers exercise).

After completion of the cognitive interviews, the domain structure for the HRQoL questionnaire remained the same, whereas the domains for the HCB questionnaire change somewhat. "Trust" and "Security/Comfort" were combined, resulting in a domain of "Trust & Security".

Once the questionnaires were revised into the final draft versions, psychometric testing was undertaken.

4.2. Part 2: Psychometric Validation

4.2.1. Sample Characteristics

The baseline characteristics of the participants included in the study are presented in Supplemental Table S1. Participants were predominantly White females (>60%) with a mean age of 48 years. The majority of participants (>60%) reported having no children in the household and owning only one dog. The highest proportion of participants were married (49.8%), working full-time (46.8%), and had a 4-years bachelor's degree or higher (~40%) with an income level of $30,000–89,999 (~51%).

The dogs on which the survey answers are based had a mean age of 7.1 years, and were owned for an average of 6.2 years. The highest proportion of participants reported taking their dog to the vet once (41%) or twice (35%) a year. Few participants reported that their dog was a service dog (5.2%). The most commonly reported dog's breed was "Mixed" (47%). Finally, most dogs were reported to be generally healthy (68%) (i.e., considered healthy by their owners), followed by those with skin problems (21%), non-food allergies (16%) and ear problems (16%).

4.2.2. Item-Level Analyses

Item-level analyses and the distribution of the canine HRQoL-Q and HCBQ total and domain scores at visit are shown in Supplemental Tables S2 and S3. All items across both questionnaires exhibited ceiling effects, such that ≥20% of the sample selected the best possible score. The canine HRQoL-Q and HCBQ total scores had a mean (SD) of 8.00 (1.59) and 8.73 (1.15), respectively.

4.2.3. Factor Structure

Findings from factor analyses supported the pre-specified domain structures of the canine HRQoL-Q and the HCBQ (Supplemental Tables S4 and S5). All items loaded onto their respective domains with factor loadings at or above 0.40. The fit statistics further supported these findings, with a CFI of 0.95, RMSEA of 0.05, and SRMR of 0.05.

4.2.4. Reliability

Internal consistency reliability was demonstrated for the canine HRQoL-Q with domain-level Cronbach's alpha values ranging between 0.81 and 0.86 for the energy and vitality, physical health, appetite and hydration, and emotional functioning domains as shown in Table 1. The mobility and cognitive function domains had a Cronbach's alpha > 0.90. The Cronbach's alpha for the social functioning domain was 0.60, with Cronbach's alphas for all items falling below <0.60. Domain-level

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Cronbach's alphas for the HCBQ ranged between 0.79 and 0.86, suggesting that the measure is internally consistent (Table 2). Item-level Cronbach's alpha values were all >0.70, with the exception of item 2d (α = 0.69). Further, all canine HRQoL-Q and HCBQ items had moderate to strong correlations (r = 0.42–0.84) with the remaining items' total score (i.e., met the pre-specified threshold of 0.30) (Table 3 and Table 4, respectively).

Table 1. Internal consistency reliability: Cronbach's alpha and Cronbach's alpha with each item deleted for the canine HRQoL questionnaire at visit 1.

Canine HRQOL Item	Total Score	Mobility	Energy and Vitality	Physical Health	Appetite and Hydration	Emotional Functioning	Cognitive Functioning	Social Functioning
My dog has difficulty moving around	0.95/0.96	0.85/0.85						
My dog has difficulty getting up	0.95/0.96	0.86/0.86						
My dog has difficulty walking	0.95/0.96	0.85/0.85						
My dog is able to jump	0.95/0.96	0.94/0.94						
My dog's energy level is the same as usual	0.95/0.96		0.84/0.84					
My dog is lethargic	0.95/0.96		0.84/0.84					
My dog is fatigued	0.95/0.96		0.81/0.81					
My dog tires quickly	0.95/0.96		0.82/0.82					
My dog's activity level is the same as usual	0.95/0.96		0.83/0.83					
My dog has skin irritation	0.96/0.96			0.82/0.82				
My dog vomits	0.96/0.96			0.83/0.83				
My dog has started having accidents	0.95/0.96			0.82/0.82				
My dog sleeps well	0.95/0.96			0.84/0.85				
My dog rests more than he/she normally does	0.95/0.96			0.81/0.81				
My dog vision seems to be getting worse	0.95/0.96			0.8/0.81				
My dog's hearing seems to be getting worse	0.95/0.96			0.8/0.81				
My dog licks/chews/scratches himself excessively	0.95/0.96			0.81/0.82				
My dog is having difficulty chewing or swallowing food	0.95/0.96			0.82/0.81				
My dog has been hungrier than usual	0.95/0.96				0.74/0.77			
My dog has been less hungry than usual	0.95/0.96				0.78/0.78			
My dog has been drinking more water than usual	0.95/0.96				0.79/0.8			
My dog has been drinking less water than usual	0.95/0.96				0.75/0.75			
My dog does not enjoy his/her usual activity	0.95/0.96					0.75/0.77		
My dog seems happy	0.95/0.96					0.76/0.77		
My dog is playful	0.95/0.96					0.79/0.8		
My dog seems fearful	0.95/0.96					0.82/0.83		
My dog seems depressed	0.95/0.96					0.73/0.75		
My dog seems to be forgetting how to do things	0.95/0.96						0.88/0.89	
My dog sometimes seems confused	0.95/0.96						0.9/0.9	
My dog seems to be forgetting people and places	0.95/0.96						0.89/0.89	
My dog seems to get stuck in corners or behind objects	0.95/0.96						0.91/0.92	
My dog greets me when I have been away	0.95/0.96							0.45/0.46
My dog likes to play with other people/dog	0.95/0.96							0.57/0.58
My dog seems to want to be alone more than usual	0.95/0.96							0.51/0.54
Cronbach's alpha (no item deleted)	0.95/0.96	0.91/0.91	0.86/0.86	0.83/0.84	0.81/0.82	0.81/0.82	0.92/0.92	0.6/0.62

Table 2. Internal consistency reliability: Cronbach's alpha and Cronbach's alpha with each item deleted for HCBQ at visit 1.

HCBQ Item	Total Score	Trust Security	Communication	Quality Time
My dog checks on me routinely	0.92/0.93	0.83/0.85		
I check on my dog routinely	0.93/0.93	0.82/0.85		
My dog is comforted by my presence	0.92/0.93	0.81/0.82		
My dog loves to be with me	0.92/0.93	0.81/0.83		

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My dog trusts me	0.92/0.93	0.82/0.83		
My dog usually seeks me out in new situations	0.93/0.94	0.87/0.88		
My dog likes positive reinforcement	0.93/0.93		0.73/0.76	
My dog makes eye contact with me	0.92/0.93		0.72/0.74	
My dog obeys my commands	0.93/0.94		0.81/0.81	
My dog and I communicate well with each other	0.92/0.93		0.69/0.72	
My dog wants to sit with me	0.93/0.93			0.85/0.85
My dog always wants me to pet him/her	0.93/0.94			0.85/0.86
My dog seeks my approval	0.93/0.93			0.84/0.85
My dog is included in my or my family's activities	0.93/0.94			0.85/0.86
I make it a priority to spend quality time with my dog	0.92/0.93			0.84/0.84
My dog and I enjoy physical activities together	0.93/0.93			0.84/0.85
I consider my dog a member of my family	0.93/0.93			0.85/0.86
My dog is my companion	0.93/0.93			0.85/0.85
My dog seeks direction from me	0.93/0.93			0.84/0.85
Cronbach's alpha (no item deleted)	0.93/0.94	0.85/0.87	0.79/0.81	0.86/0.87

Table 3. Internal consistency reliability: item-total correlations for the canine HRQoL questionnaire at visit 1.

Canine HRQOL Item	Total Score	Mobility	Energy and Vitality	Physical Health	Appetite and Hydration	Emotional Functioning	Cognitive Functioning	Social Functioning
My dog has difficulty moving around	0.784 (<0.0001)	0.925 (<0.0001)						
My dog has difficulty getting up	0.746 (<0.0001)	0.911 (<0.0001)						
My dog has difficulty walking	0.784 (<0.0001)	0.93 (<0.0001)						
My dog is able to jump	0.556 (<0.0001)	0.773 (<0.0001)						
My dog's energy level is the same as usual	0.592 (<0.0001)		0.77 (<0.0001)					
My dog is lethargic	0.714 (<0.0001)		0.769 (<0.0001)					
My dog is fatigued	0.769 (<0.0001)		0.833 (<0.0001)					
My dog tires quickly	0.713 (<0.0001)		0.832 (<0.0001)					
My dog's activity level is the same as usual	0.611 (<0.0001)		0.786 (<0.0001)					
My dog has skin irritation	0.525 (<0.0001)			0.678 (<0.0001)				
My dog vomits	0.44 (<0.0001)			0.549 (<0.0001)				
My dog has started having accidents	0.587 (<0.0001)			0.644 (<0.0001)				
My dog sleeps well	0.46 (<0.0001)			0.421 (<0.0001)				
My dog rests more than he/she normally does	0.74 (<0.0001)			0.72 (<0.0001)				
My dog vision seems to be getting worse	0.75 (<0.0001)			0.761 (<0.0001)				
My dog's hearing seems to be getting worse	0.72 (<0.0001)			0.744 (<0.0001)				
My dog licks/chews/scratches himself excessively	0.521 (<0.0001)			0.723 (<0.0001)				
My dog is having difficulty chewing or swallowing food	0.667 (<0.0001)			0.67 (<0.0001)				
My dog has been hungrier than usual	0.616 (<0.0001)				0.834 (<0.0001)			
My dog has been less hungry than usual	0.647 (<0.0001)				0.779 (<0.0001)			
My dog has been drinking more water than usual	0.643 (<0.0001)				0.81 (<0.0001)			
My dog has been drinking less water than usual	0.659 (<0.0001)				0.806 (<0.0001)			
My dog does not enjoy his/her usual activity	0.649 (<0.0001)					0.806 (<0.0001)		
My dog seems happy	0.626 (<0.0001)					0.771 (<0.0001)		
My dog is playful	0.677 (<0.0001)					0.712 (<0.0001)		
My dog seems fearful	0.486 (<0.0001)					0.679 (<0.0001)		
My dog seems depressed	0.687 (<0.0001)					0.836 (<0.0001)		
My dog seems to be forgetting how to do things	0.751 (<0.0001)						0.922 (<0.0001)	
My dog sometimes seems confused	0.77 (<0.0001)						0.908 (<0.0001)	
My dog seems to be forgetting people and places	0.728 (<0.0001)						0.911 (<0.0001)	
My dog seems to get stuck in corners or behind objects	0.711 (<0.0001)						0.868 (<0.0001)	

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My dog greets me when I have been away	0.419 (<0.0001)			0.731 (<0.0001)
My dog likes to play with other people/dog	0.539 (<0.0001)			0.8 (<0.0001)
My dog seems to want to be alone more than usual	0.614 (<0.0001)			0.722 (<0.0001)

Table 4. Internal consistency reliability: item-total correlations for the HCBQ at visit 1.

HCBQ Item	Total Score	Trust Security	Communication	Quality Time
My dog checks on me routinely	0.698 (<0.0001)	0.763 (<0.0001)		
I check on my dog routinely	0.691 (<0.0001)	0.761 (<0.0001)		
My dog is comforted by my presence	0.761 (<0.0001)	0.839 (<0.0001)		
My dog loves to be with me	0.761 (<0.0001)	0.801 (<0.0001)		
My dog trusts me	0.746 (<0.0001)	0.791 (<0.0001)		
My dog usually seeks me out in new situations	0.539 (<0.0001)	0.687 (<0.0001)		
My dog likes positive reinforcement	0.675 (<0.0001)		0.772 (<0.0001)	
My dog makes eye contact with me	0.758 (<0.0001)		0.786 (<0.0001)	
My dog obeys my commands	0.601 (<0.0001)		0.781 (<0.0001)	
My dog and I communicate well with each other	0.76 (<0.0001)		0.832 (<0.0001)	
My dog wants to sit with me	0.672 (<0.0001)			0.678 (<0.0001)
My dog always wants me to pet him/her	0.603 (<0.0001)			0.645 (<0.0001)
My dog seeks my approval	0.7 (<0.0001)			0.755 (<0.0001)
My dog is included in my or my family's activities	0.608 (<0.0001)			0.678 (<0.0001)
I make it a priority to spend quality time with my dog	0.712 (<0.0001)			0.73 (<0.0001)
My dog and I enjoy physical activities together	0.684 (<0.0001)			0.733 (<0.0001)
I consider my dog a member of my family	0.603 (<0.0001)			0.594 (<0.0001)
My dog is my companion	0.686 (<0.0001)			0.682 (<0.0001)
My dog seeks direction from me	0.685 (<0.0001)			0.736 (<0.0001)

For the canine HRQoL-Q, test-retest reliability was demonstrated among n = 54 dogs whose owners reported no change on the OGIH for the total score and the mobility and physical health domains, with an ICC value of >0.80 (Table 5). Further, the ICC for the energy and vitality, emotional functioning and social functioning domains was acceptable-to-good (0.79–0.80), although the 95% confidence intervals were wider with a 95% lower bound of <0.70. Somewhat lower ICCs were observed for the appetite and hydration and cognitive functioning domains (0.66 and 0.65, respectively), with 95% lower bounds of 0.47 and 0.46, respectively, suggesting poor reproducibility for these domains. There were minimal score changes between visits 1 and 2 for all scores. Test-retest reliability for the HCBQ was moderate overall, as demonstrated in Table 6. While only small decreases in total and domain scores were observed between visits 1 and 2, ICCs between 0.70–0.77 (with 95% confidence interval lower bounds < 0.70) were demonstrated for the total score and the communication and quality time domains. The trust domain demonstrated poor reproducibility (ICC: 0.58; 95% confidence interval: 0.37–0.73).

Table 5. Test-retest reliability: mean scores and mean change in the canine HRQoL questionnaire scores from visit 1 to visit 2 with ICCs for dogs defined as stable based on the OGIH.

Canine HRQoL Questionnaire Score	N	Mean (SD) at Visit 1	Mean (SD) at Visit 2	Mean Change (SD)	ICC (95% CI)
Canine HRQoL—Mobility subscore	54	8.65 (2.02)	8.52 (1.94)	−0.13 (1.09)	0.85 (0.75–0.91)
Canine HRQoL—Energy/vitality subscore	54	7.70 (2.13)	7.45 (1.99)	−0.25 (1.3)	0.80 (0.68–0.88)
Canine HRQoL—Physical health subscore	54	7.99 (1.60)	7.55 (1.71)	−0.44 (0.9)	0.85 (0.76–0.91)
Canine HRQoL—Appetite subscore	54	7.99 (1.79)	7.66 (1.88)	−0.32 (1.52)	0.66 (0.47–0.78)
Canine HRQoL–Emotional functioning subscore	54	8.34 (1.71)	7.99 (1.68)	−0.35 (1.11)	0.79 (0.66–0.87)
Canine HRQoL—Cognitive functioning subscore	54	8.91 (1.46)	8.65 (1.75)	−0.27 (1.35)	0.65 (0.46–0.78)
Canine HRQoL—Social functioning subscore	54	8.15 (1.72)	7.95 (1.80)	−0.20 (1.11)	0.80 (0.68–0.88)
Canine HRQoL—General health subscore	54	8.76 (1.36)	8.55 (1.32)	−0.21 (0.65)	0.88 (0.81–0.93)
Canine HRQoL—Total score	54	8.20 (1.47)	7.89 (1.54)	−0.31 (0.63)	0.91 (0.86–0.95)

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Table 6. Test-retest reliability: mean scores and mean change in the HCBQ scores from visit 1 to visit 2 with ICCs for dogs defined as stable based on the OGIH.

HCBQ Score	N	Mean (SD) at Visit 1	Mean (SD) at Visit 2	Mean Change (SD)	ICC (95% CI)
HCBQ—Trust/security subscore	54	8.99 (1.11)	8.89 (1.32)	−0.10 (1.12)	0.58 (0.37–0.73)
HCBQ—Communication subscore	54	8.77 (1.21)	8.74 (1.19)	−0.03 (0.82)	0.77 (0.63–0.86)
HCBQ—Quality time subscore	54	8.77 (1.19)	8.61 (1.17)	−0.16 (0.83)	0.75 (0.61–0.85)
HCBQ—General bonding subscore	54	9.64 (0.66)	9.48 (0.80)	−0.16 (0.56)	0.70 (0.54–0.82)
HCBQ—Total score	54	8.84 (1.06)	8.72 (1.10)	−0.12 (0.75)	0.76 (0.62–0.85)

4.2.5. Validity

Regarding known-groups validity, the canine HRQoL-Q was able to differentiate between dogs ($p < 0.01$) based on canine health/disease state, OGIH ratings, and canine general health and HRQoL (Table 7). Specifically, significant differences ($p < 0.001$) in the total score, and the mobility, energy and vitality, physical health and emotional functioning domains were observed at visit 1 between groups defined by canine health/disease states in the expected direction (i.e., healthy dogs had higher [better] scores, compared to dogs with non-food allergies/skin problems and ear infections). No significant differences were observed for the appetite and hydration, social functioning and cognitive functioning domains. When canine HRQoL questionnaire scores were compared across OGIH group categories, it was evident that dogs whose owners reported them being in "excellent" health had significantly higher (better) scores, compared to those in "poor/fair" health. Finally, dogs with better health and a higher HRQoL per the canine HRQoL questionnaire general health and quality of life items had significantly higher (better) scores, compared to those in poor health/with a poor quality of life. Strong effect sizes were shown for the OGIH and canine HRQoL questionnaire general health and bonding items for all domain scores and for the total score. Similar findings were observed for the HCBQ (Table 8), such that total and domain scores were significantly different between OGIH groups and by the general bonding items (with higher scores observed among dogs whose owners reported them being in excellent health and with a higher degree of bonding). However, there were no significant differences in scores between canine health/disease state groups.

Table 7. Known-groups validity: comparison of the canine HRQoL questionnaire scores between severity groups defined by the dog's health/disease state, age, OGIH and general health items at visit 1.

Canine HRQoL Questionnaire Score	Group Definition	n	Mean (SD)	*p*-Value	Effect Size, η^2
Mobility	**Canine Health/Disease States**				
	Healthy	204	8.76 (1.79)		
	Non-food allergy/skin problems	62	7.88 (2.64)	<0.0001	0.07
	Ear infection	16	6.76 (2.85)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.76 (1.99)		
	Tertile 2 (4.5–8.5 years)	110	8.91 (1.61)	<0.0001	0.10
	Tertile 3 (≥8.5 years)	108	7.31 (2.72)		
	OGIH				
	Excellent	96	9.27 (1.65)		
	Very good	147	8.79 (1.73)	<0.0001	0.31
	Good	64	7.13 (2.17)		
	Fair/poor	20	4.34 (2.86)		
	Canine HRQoL questionnaire—item 8a				
	Tertile 1 (<8)	76	6.23 (2.73)		
	Tertile 2 (8–9)	173	8.72 (1.75)	<0.0001	0.28
	Tertile 3 (10)	78	9.51 (1.25)		
	Canine HRQoL questionnaire—item 8b				
	Tertile 1 (<9)	95	6.88 (2.71)		
	Tertile 2 (9)	86	8.31 (1.97)	<0.0001	0.20
	Tertile 3 (10)	146	9.29 (1.48)		
Energy and vitality	**Canine health/disease states**				

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	Healthy	204	8.10 (1.73)		
	Non-food allergy/skin problems	62	7.15 (2.28)	<0.0001	0.08
	Ear infection	16	6.13 (2.76)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.22 (2.00)		
	Tertile 2 (4.5–8.5 years)	110	8.00 (1.74)	<0.0001	0.10
	Tertile 3 (≥8.5 years)	108	6.70 (2.18)		
	OGIH				
	Excellent	96	8.82 (1.80)		
	Very good	147	7.82 (1.64)	<0.0001	0.33
	Good	64	6.60 (1.79)		
	Fair/poor	20	4.08 (1.62)		
	Canine HRQoL questionnaire—item 8a				
	Tertile 1 (<8)	76	5.68 (2.01)		
	Tertile 2 (8–9)	173	7.93 (1.67)	<0.0001	0.31
	Tertile 3 (10)	78	8.94 (1.61)		
	Canine HRQoL questionnaire—item 8b				
	Tertile 1 (<9)	95	6.25 (2.08)		
	Tertile 2 (9)	86	7.55 (1.74)	<0.0001	0.23
	Tertile 3 (10)	146	8.62 (1.72)		
Physical health	**Canine health/disease states**				
	Healthy	204	8.16 (1.67)		
	Non-food allergy/skin problems	62	6.55 (1.52)	<0.0001	0.14
	Ear infection	16	7.36 (1.80)		
	Age				
	Tertile 1 (≤4.5 years)	109	7.97 (2.00)		
	Tertile 2 (4.5–8.5 years)	110	7.87 (1.53)	<0.0001	0.08
	Tertile 3 (≥8.5 years)	108	6.83 (1.84)		
	OGIH				
	Excellent	96	8.61 (1.78)		
	Very good	147	7.74 (1.46)	<0.0001	0.30
	Good	64	6.41 (1.48)		
	Fair/poor	20	4.89 (1.52)		
	Canine HRQoL questionnaire—item 8a				
	Tertile 1 (<8)	76	6.02 (1.63)		
	Tertile 2 (8–9)	173	7.71 (1.57)	<0.0001	0.26
	Tertile 3 (10)	78	8.74 (1.69)		
	Canine HRQoL questionnaire—item 8b				
	Tertile 1 (<9)	95	6.36 (1.82)		
	Tertile 2 (9)	86	7.52 (1.58)	<0.0001	0.21
	Tertile 3 (10)	146	8.37 (1.62)		
Appetite and hydration	**Canine health/disease states**				
	Healthy	204	8.09 (1.93)		
	Non-food allergy/skin problems	62	7.71 (1.75)	0.35	0.01
	Ear infection	16	7.81 (1.44)		
	Age				
	Tertile 1 (≤4.5 years)	109	7.99 (2.18)		
	Tertile 2 (4.5–8.5 years)	110	8.10 (1.69)	0.06	0.02
	Tertile 3 (≥8.5 years)	108	7.53 (1.73)		
	OGIH				
	Excellent	96	8.72 (1.88)		
	Very good	147	8.04 (1.61)	<0.0001	0.19
	Good	64	6.82 (1.81)		
	Fair/poor	20	5.97 (1.22)		
	Canine HRQoL questionnaire—item 8a				
	Tertile 1 (<8)	76	6.61 (1.68)		
	Tertile 2 (8–9)	173	7.95 (1.75)	<0.0001	0.18
	Tertile 3 (10)	78	8.93 (1.69)		
	Canine HRQoL questionnaire—item 8b				
	Tertile 1 (<9)	95	6.60 (1.68)		
	Tertile 2 (9)	86	7.89 (1.79)	<0.0001	0.22
	Tertile 3 (10)	146	8.69 (1.61)		
Emotional functioning	**Canine health/disease states**				

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	Healthy	204	8.52 (1.59)		
	Non-food allergy/skin problems	62	7.85 (1.59)	0.01	0.03
	Ear infection	16	8.16 (1.48)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.34 (1.96)		
	Tertile 2 (4.5–8.5 years)	110	8.61 (1.30)	0.002	0.04
	Tertile 3 (≥8.5 years)	108	7.83 (1.56)		
	OGIH				
	Excellent	96	9.16 (1.47)		
	Very good	147	8.43 (1.37)	<0.0001	0.30
	Good	64	7.30 (1.35)		
	Fair/poor	20	5.78 (1.39)		
	Canine HRQoL questionnaire—item 8a				
	Tertile 1 (<8)	76	6.87 (1.56)		
	Tertile 2 (8–9)	173	8.45 (1.39)	<0.0001	0.25
	Tertile 3 (10)	78	9.22 (1.42)		
	Canine HRQoL questionnaire—item 8b				
	Tertile 1 (<9)	95	7.04 (1.55)		
	Tertile 2 (9)	86	8.15 (1.46)	<0.0001	0.28
	Tertile 3 (10)	146	9.13 (1.28)		
Cognitive functioning	**Canine health/disease states**				
	Healthy	204	8.92 (1.76)		
	Non-food allergy/skin problems	62	8.51 (2.16)	0.26	0.01
	Ear infection	16	8.59 (1.34)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.70 (2.19)		
	Tertile 2 (4.5–8.5 years)	110	9.13 (1.23)	0.004	0.03
	Tertile 3 (≥8.5 years)	108	8.25 (2.20)		
	OGIH				
	Excellent	96	9.28 (1.92)		
	Very good	147	9.06 (1.35)	<0.0001	0.17
	Good	64	7.64 (2.13)		
	Fair/poor	20	6.63 (2.58)		
	Canine HRQoL questionnaire—item 8a				
	Tertile 1 (<8)	76	7.40 (2.29)		
	Tertile 2 (8–9)	173	9.02 (1.50)	<0.0001	0.14
	Tertile 3 (10)	78	9.23 (1.94)		
	Canine HRQoL questionnaire—item 8b				
	Tertile 1 (<9)	95	7.41 (2.23)		
	Tertile 2 (9)	86	8.88 (1.59)	<0.0001	0.19
	Tertile 3 (10)	146	9.42 (1.49)		
Social functioning	**Canine health/disease states**				
	Healthy	204	8.40 (1.64)		
	Non-food allergy/skin problems	62	7.97 (2.26)	0.21	0.01
	Ear infection	16	8.00 (1.82)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.51 (1.70)		
	Tertile 2 (4.5–8.5 years)	110	8.61 (1.49)	<0.001	0.06
	Tertile 3 (≥8.5 years)	108	7.69 (1.79)		
	OGIH				
	Excellent	96	9.14 (1.41)		
	Very good	147	8.35 (1.51)	<0.0001	0.23
	Good	64	7.50 (1.53)		
	Fair/poor	20	5.96 (1.84)		
	Canine HRQoL questionnaire—item 8a				
	Tertile 1 (<8)	76	7.06 (1.76)		
	Tertile 2 (8–9)	173	8.40 (1.54)	<0.0001	0.18
	Tertile 3 (10)	78	9.16 (1.35)		
	Canine HRQoL questionnaire—item 8b				
	Tertile 1 (<9)	95	7.20 (1.79)		
	Tertile 2 (9)	86	8.28 (1.49)	<0.0001	0.19
	Tertile 3 (10)	146	8.96 (1.40)		
Total score	**Canine health/disease states**				
	Healthy	204	8.38 (1.41)		

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	Non-food allergy/skin problems	62	7.48 (1.59)	<0.0001	0.07
	Ear infection	16	7.48 (1.61)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.29 (1.75)		
	Tertile 2 (4.5–8.5 years)	110	8.36 (1.21)	<0.0001	0.09
	Tertile 3 (≥8.5 years)	108	7.34 (1.57)		
	OGIH				
	Excellent	96	8.94 (1.42)		
	Very good	147	8.22 (1.14)	<0.0001	0.38
	Good	64	6.94 (1.27)		
	Fair/poor	20	5.26 (1.23)		
	Canine HRQoL questionnaire—item 8a				
	Tertile 1 (<8)	76	6.44 (1.47)		
	Tertile 2 (8–9)	173	8.21 (1.24)	<0.0001	0.34
	Tertile 3 (10)	78	9.05 (1.26)		
	Canine HRQoL questionnaire—item 8b				
	Tertile 1 (<9)	95	6.73 (1.57)		
	Tertile 2 (9)	86	7.98 (1.26)	<0.0001	0.31
	Tertile 3 (10)	146	8.84 (1.18)		

Table 8. Known-groups validity: comparison of the canine HRQoL questionnaire scores between severity groups defined by the dog's health/disease state, age, OGIH and general bonding item at visit 1.

HCBQ Score	Group Definition	n	Mean (SD)	*p*-Value	Effect Size, η^2
Trust and Security	**Canine Health/Disease States**				
	Healthy	204	8.87 (1.24)		
	Non-food allergy/skin problems	62	9.13 (1.04)	0.19	0.01
	Ear infection	16	9.24 (0.95)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.96 (1.33)		
	Tertile 2 (4.5–8.5 years)	110	9.07 (1.01)	0.46	0.00
	Tertile 3 (≥8.5 years)	108	8.87 (1.18)		
	OGIH				
	Excellent	96	9.47 (0.90)		
	Very good	147	9.01 (1.10)	<0.0001	0.13
	Good	64	8.31 (1.34)		
	Fair/poor	20	8.40 (1.24)		
	HCBQ—item 4a				
	Below median (≤9)	115	8.12 (1.28)	<0.0001	0.28
	Above median (10)	212	9.43 (0.81)		
	HCBQ—item 4b				
	Below median (≤9)	103	8.10 (1.29)	<0.0001	0.25
	Above median (10)	224	9.37 (0.87)		
Communication	**Canine health/disease states**				
	Healthy	204	8.73 (1.31)		
	Non-food allergy/skin problems	62	8.48 (1.24)	0.31	0.01
	Ear infection	16	8.91 (0.81)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.74 (1.39)		
	Tertile 2 (4.5–8.5 years)	110	8.80 (1.14)	0.23	0.01
	Tertile 3 (≥8.5 years)	108	8.51 (1.36)		

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	OGIH				
	Excellent	96	9.45 (0.90)		
	Very good	147	8.69 (1.18)	<0.0001	0.22
	Good	64	7.78 (1.30)		
	Fair/poor	20	7.88 (1.58)		
	HCBQ—item 4a				
	Below median (≤9)	115	7.83 (1.35)	<0.0001	0.24
	Above median (10)	212	9.15 (1.01)		
	HCBQ—item 4b				
	Below median (≤9)	103	7.78 (1.34)	<0.0001	0.22
	Above median (10)	224	9.10 (1.05)		
Spending quality time/companionship	**Canine health/disease states**				
	Healthy	204	8.60 (1.32)		
	Non-food allergy/skin problems	62	8.52 (1.18)	0.87	0.00
	Ear infection	16	8.47 (1.22)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.80 (1.29)		
	Tertile 2 (4.5–8.5 years)	110	8.73 (1.05)	0.002	0.04
	Tertile 3 (≥8.5 years)	108	8.23 (1.43)		
	OGIH				
	Excellent	96	9.28 (0.94)		
	Very good	147	8.64 (1.11)	<0.0001	0.21
	Good	64	8.64 (1.11)		
	Fair/poor	20	7.78 (1.55)		
	HCBQ—item 4a				
	Below median (≤9)	115	7.67 (1.28)	<0.0001	0.27
	Above median (10)	212	9.08 (0.99)		
	HCBQ—item 4b				
	Below median (≤9)	103	7.62 (1.23)	<0.0001	0.26
	Above median (10)	224	9.03 (1.05)		
Total score	**Canine health/disease states**				
	Healthy	204	8.71 (1.19)		
	Non-food allergy/skin problems	62	8.70 (1.02)	0.95	0.00
	Ear infection	16	8.81 (0.95)		
	Age				
	Tertile 1 (≤4.5 years)	109	8.84 (1.24)		
	Tertile 2 (4.5–8.5 years)	110	8.85 (0.94)	0.03	0.02
	Tertile 3 (≥8.5 years)	108	8.49 (1.22)		
	OGIH				
	Excellent	96	9.38 (0.82)		
	Very good	147	8.76 (1.00)	<0.0001	0.22
	Good	64	7.90 (1.23)		
	Fair/poor	20	7.99 (1.32)		
	HCBQ—item 4a				
	Below median (≤9)	115	7.85 (1.19)	<0.0001	0.32

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	Above median (10)	212	9.20 (0.80)		
	HCBQ—item 4b				
	Below median (≤9)	103	7.81 (1.16)	<0.0001	0.29
	Above median (10)	224	9.15 (0.87)		

The matrix of inter-correlations of the canine HRQoL-Q total/domain scores and the HCBQ total/domain scores are shown in Tables 9 and 10. Moderate-to-strong correlations were observed between all the canine HRQoL questionnaire domains, with especially strong correlations observed between the mobility and energy/vitality domains (r = 0.73), and between the physical health and both the appetite and hydration (r = 0.70) and cognitive functioning (r = 0.72) domains. Strong correlations were also observed between the total score and all but the general health domain. For the HCBQ, a strong correlation was observed between the trust/security domain and both the communication (r = 0.74) and quality time (r = 0.75) domains. Further, a strong correlation of r = 0.75 was demonstrated between the communication domain and the quality time domain. Similarly to the canine HRQoL-Q, very strong correlations (r > 0.87) were observed between each of the HCBQ domains and the total score, with the exception of the general bonding domain (r = 0.64). Overall, these findings provide strong support for the convergent validity of the measures. Finally, the canine HRQoL-Q was moderately correlated with the HCBQ (r = 0.44).

Table 9. Convergent validity: correlations among the canine HRQoL questionnaire total and HRQoL domain scores at visit 1.

Domain	Mobility	Energy and Vitality	Physical Health	Appetite	Emotional Functioning	Cognitive Functioning	Social Functioning	General Health	Total Score
Mobility subscore	1.00 (<0.0001)	0.73 (<0.0001)	0.65 (<0.0001)	0.51 (<0.0001)	0.58 (<0.0001)	0.64 (<0.0001)	0.52 (<0.0001)	−0.62 (<0.0001)	0.81 (<0.0001)
Energy/vitality subscore	0.73 (<0.0001)	1.00 (<0.0001)	0.68 (<0.0001)	0.57 (<0.0001)	0.66 (<0.0001)	0.63 (<0.0001)	0.59 (<0.0001)	−0.62 (<0.0001)	0.85 (<0.0001)
Physical health subscore	0.65 (<0.0001)	0.68 (<0.0001)	1.00 (<0.0001)	0.70 (<0.0001)	0.66 (<0.0001)	0.72 (<0.0001)	0.52 (<0.0001)	−0.60 (<0.0001)	0.90 (<0.0001)
Appetite subscore	0.51 (<0.0001)	0.57 (<0.0001)	0.70 (<0.0001)	1.00 (<0.0001)	0.67 (<0.0001)	0.62 (<0.0001)	0.52 (<0.0001)	−0.50 (<0.0001)	0.79 (<0.0001)
Emotional functioning subscore	0.58 (<0.0001)	0.66 (<0.0001)	0.66 (<0.0001)	0.67 (<0.0001)	1.00 (<0.0001)	0.58 (<0.0001)	0.62 (<0.0001)	−0.59 (<0.0001)	0.82 (<0.0001)
Cognitive functioning subscore	0.64 (<0.0001)	0.63 (<0.0001)	0.72 (<0.0001)	0.62 (<0.0001)	0.58 (<0.0001)	1.00 (<0.0001)	0.53 (<0.0001)	−0.51 (<0.0001)	0.82 (<0.0001)
Social functioning subscore	0.52 (<0.0001)	0.59 (<0.0001)	0.52 (<0.0001)	0.52 (<0.0001)	0.62 (<0.0001)	0.53 (<0.0001)	1.00 (<0.0001)	−0.48 (<0.0001)	0.70 (<0.0001)
General health subscore	−0.62 (<0.0001)	−0.62 (<0.0001)	−0.60 (<0.0001)	−0.50 (<0.0001)	−0.59 (<0.0001)	−0.51 (<0.0001)	−0.48 (<0.0001)	1.00 (<0.0001)	−0.69 (<0.0001)
Total score	0.81 (<0.0001)	0.85 (<0.0001)	0.90 (<0.0001)	0.79 (<0.0001)	0.82 (<0.0001)	0.82 (<0.0001)	0.70 (<0.0001)	−0.69 (<0.0001)	1.00 (<0.0001)

Table 10. Convergent validity: correlations among the HCBQ total and HCBQ domain scores at visit 1.

Domain	Trust Security	Communication	Quality Time	General Bonding	Total Score
Trust/security subscore	1.00 (<0.0001)	0.74 (<0.0001)	0.75 (<0.0001)	0.61 (<0.0001)	0.90 (<0.0001)
Communication subscore	0.74 (<0.0001)	1.00 (<0.0001)	0.75 (<0.0001)	0.55 (<0.0001)	0.87 (<0.0001)
Quality time subscore	0.75 (<0.0001)	0.75 (<0.0001)	1.00 (<0.0001)	0.60 (<0.0001)	0.95 (<0.0001)
General bonding subscore	0.61 (<0.0001)	0.55 (<0.0001)	0.60 (<0.0001)	1.00 (<0.0001)	0.64 (<0.0001)
Total score	0.90 (<0.0001)	0.87 (<0.0001)	0.95 (<0.0001)	0.64 (<0.0001)	1.00 (<0.0001)

5. Discussion

This study aimed to develop and validate two questionnaires, a canine HRQoL questionnaire and a human-canine bond questionnaire, to assess the overall health and well-being of dogs for use

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in veterinary clinics. The questionnaires aim to encourage discussions, alert the veterinarian and pet caretaker to potential health issues, and support decision-making on recommended actions, e.g., treatment, dietary changes, need for further testing, end of life decisions, and improve veterinary care. Development of two questionnaires, one focusing directly on health-related quality of life and a second focused on the bond between caretaker and dog, was undertaken based on existing literature that supports the hypothesis that, while the bond is a separate construct from HRQoL, the bond is related to and has an impact on the health-related quality of life of the canine.

By adopting established regulatory and industry guidelines to support development of clinical outcome assessment measures for human drug approval, two valid and reliable measures have been developed that can be used in a single veterinary clinic to improve health outcomes and monitor the health and well-being of its canine patients over time or across multiple veterinary clinics to compare canine health and well-being in a variety of settings or geographies. Data obtained from individual evaluations can be aggregated to establish normative population data to help veterinarians and caretakers to understand how a dog's scores compare with others in the database and deficits in the dog's HRQoL that should be investigated further.

Development of valid and reliable questionnaires began with understanding what to measure from the perspective of dog caretakers, veterinarians, and existing literature. Interviews with veterinarians and focus groups with dog caretakers combined with the use of multiple modes of qualitative data collection (e.g., photo-collages, ranking task) provided in-depth understanding of caretakers' experiences with their dogs and helped identify concepts important to caretakers for assessing a dog's HRQoL, as well as the bond between the caretaker and dog. Results were used to develop a preliminary domain structure and to generate items for the two initial draft questionnaires. Based on the content of the items and caretakers' descriptions of their experiences with their dogs, a preliminary recall period, scale and response options were selected for the draft questionnaires.

Once draft questionnaires were developed, individual cognitive interviews with additional dog caretakers were conducted to assess the content validity and refine the questionnaires when issues were identified. Interviews proceeded until no additional revisions were indicated and content validity was established.

Based on cognitive interviews/input from dog caregivers, a few items in the draft questionnaires were moved from one domain to another, removed, or reworded. Two domains in the draft HCBQ (i.e., "Trust" and "Security/Comfort") were combined into a single "Trust and Security" domain for reasons of efficiency and similarity of concepts perceived to be relevant to these domains.

Following demonstration of content validity, quantitative, psychometric testing of the performance of both the canine HRQoL-Q and the HCBQ was undertaken in a non-interventional prospective survey study with participants recruited using similar criteria used for the qualitative research phase. Performance testing of both questionnaires indicated the presence of ceiling effects, such that >20% of caregivers of dogs selected the best possible score. These findings are expected, given that the dogs on which the survey is based are predominantly healthy. Thus, a high percentage of respondents may have accurately reported that their dog did not experience any issues. The average scores for the canine HRQoL-Q and the HCBQ (8.00 and 8.73, respectively) were close to the maximum possible score of 10, suggesting that dogs in the study generally had a high quality of life and bonded well with their caretaker. The pre-specified factor structure of both the canine HRQoL-Q and the HCBQ was also confirmed using a factor analysis, although some items exhibited lower factor loadings. Such items were considered for removal in unison with findings from other psychometric analyses.

Upon additional testing, the canine HRQoL-Q demonstrated strong internal consistency on all but the social functioning domain. This could indicate that the social functioning items may not be contributing useful information to the canine HRQoL-Q; thus this domain was considered for removal from the measure. Further, the mobility and cognitive functioning domains had a Cronbach's alpha value >0.90, indicating that some items within each of these domains may be redundant and can be eliminated from the measure. Item-total correlations were moderate-to-strong for all items in the canine HRQoL-Q. The HCBQ was also shown to be internally consistent. In unison,

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these findings showed that items within the measures generally reflect a single underlying construct and consistent item responses.

Reproducibility of the canine HRQoL-Q was strong, as evidenced by an ICC >0.79 and a minimal change in scores between visits 1 and 2. This is a strong result considering the relatively small subsample of dogs available for the analysis (n = 54) who did not exhibit change in their health per their owner's report. However, the appetite and hydration and cognitive functioning domains demonstrated somewhat poor reproducibility, thus highlighting these domains as potential candidates for removal from the measure. Test-retest reliability for the HCBQ was moderate overall, with ICCs between 0.70–0.79 (and 95% confidence interval lower bounds <0.70) demonstrated for the total score and the communication and quality time domains. The HCBQ trust domain showed poor reproducibility; however, this domain was ultimately retained in the measure given that the remaining analyses indicated generally strong psychometric properties. Despite moderate support for test-retest reliability for both measures, the change in scores was overall low between the two time points, potentially supporting natural variations in canine health and the HCB over a 2-week period.

Strong support was also found for the known-groups validity of the canine HRQoL-Q and the HCBQ. The canine HRQoL-Q was able to differentiate between groups as defined by canine health/disease states, with higher scores observed among healthy dogs, as expected. However, no significant differences were observed for the appetite and hydration, social functioning and cognitive functioning domains, potentially suggesting that these domains may not be affected by the disease states included in our study. Nonetheless, significant differences were observed for all canine HRQoL-Q domains by groups defined by the OGIH and canine general HRQoL/health, providing support for known-groups validity overall.

Similarly, HCBQ scores were not significantly different by canine health/disease state, as the HCB may not be impacted by condition, and indeed may even be stronger among sick dogs. However, total/domain scores differed significantly by the OGIH and general bonding items, with higher scores observed among dogs whose owners reported that their dog was in "excellent" health and whose owners reported a higher degree of bonding with their dog as anticipated. These findings overall indicate that Canine HRQoL-Q scores have somewhat of a semi-predictable curve. However, HCBQ scores do not follow the same pattern, and will largely depend on conditions at home.

Convergent validity, a measure of the degree concepts are related, was supported by moderate-to-strong and significant correlations between concepts indicating that these concepts are measuring the same construct, health-related quality of life of the dog. In addition, the canine HRQoL-Q global score was found to be moderately, significantly, and positively correlated with the HCBQ total score (Pearson correlation coefficient = 0.44, $p < 0.0001$), demonstrating that there is convergent validity between the concepts of canine HRQoL and concepts in the HCBQ. This finding indicates that the concepts of HRQoL and HCB are related and a moderate correlation is to be expected if each measure also contributes uniquely to the concepts of interest. This relationship also suggests the two measures together may measure a broader concept, e.g., overall health and well-being of the dog. Further, this suggests that the availability of both measures in veterinary clinics can promote a broader, more comprehensive discussion about factors that influence a dog's overall health, quality of life, and welfare than either measure alone.

Psychometric testing of the canine HRQoL-Q and HCBQ indicated that some items might not reflect concepts that are prevalent enough among healthy dogs to warrant inclusion in a measure aimed at assessing generic HRQoL or the HCB. These concepts may have been identified during concept elicitation because only certain dogs specifically experienced them or were present in the relationship among only select dogs and their caregivers. In unison, findings from psychometric analyses suggested that the deletion of some items/domains which are not adding informational content to the scales may improve the psychometric properties of each of the tools, leading to a final set of shorter questionnaires for ease of use in veterinarian clinics. As such, various items, as well as the underperforming appetite and hydration/social functioning domains were removed from the measures. The final instruments were retested and showed improved or similar psychometrics, providing support for the scoring algorithm.

There are several strengths in the creation of the HRQoL-Q and HCBQ. A major strength of this study was the rigorous development process, using the principles and good research practices for development of outcomes measures outlined in FDA guidances for the development of new drugs. Using this approach, the qualitative research conducted with dog caretakers provided in-depth understanding of dog-specific HRQoL concepts from caretakers who are best positioned to assess the HRQoL of their dogs and who will complete the questionnaires in the veterinary office. Combining this data from caretakers with a literature review and data from interviews with veterinarians provided a rich foundation for item generation and development of draft questionnaires. Piloting the draft questionnaires with caretakers to revise the questionnaire before quantitative testing was also a strength of the development process. Including the caretaker's perspective and language early on in the development process helped to ensure the relevancy, comprehensiveness, and ease of use of these questionnaires in veterinary practice.

While there is bias inherent in qualitative research, the research team designed the interview and focus group discussion guides to contain open-ended and non-leading questions to minimize bias in the data collection process. To minimize bias associated with the order of completion of the questionnaires in the cognitive interviews, the order was counterbalanced (i.e., the participant completed the HRQoL-Q first, followed by the HCBQ, or vice versa). To ensure the accuracy of and minimize bias associated with the summary notes for each part of qualitative data collection, the study members debriefed after the focus group or interview, and shared notes amongst the team to align on findings. Additionally, ensuring that content experts (i.e., veterinarians) were involved in the development process ensured the concepts assessed in the measures were relevant to both caregivers and veterinarians. Furthermore, involving dog caregivers of various sociodemographic backgrounds and dog of varying sizes, breeds, ages, and health status strengthened the content validation process.

Strengths of the psychometric validation study include the relatively large sample size recruited which enabled the assessment of all planned psychometric properties robustly. The use of diversity quotas also ensured that the convenience sample is representative of the U.S. population and the measurement properties of both tools are expected to be generalizable. An additional strength of the study relates to the development of the HCBQ to help understand the HRQoL of dogs. The HCBQ provides unique and important insights on concepts that potentially impact a dog's HRQoL and have not been measured in the past for this purpose. To our knowledge, the HCBQ is the first questionnaire shown to be valid and reliable for assessing the bond between caretakers and their dogs.

Some limitations to the study should also be acknowledged. Participants in the qualitative research to develop the draft questionnaires were a convenience sample recruited from a single, albeit large, clinical research company, which could potentially impact generalizability and replicability of the analysis and study findings. Although efforts were made to recruit caretakers with a diverse sample of dogs, the sample may not represent the entire population of dogs (in terms of breed, size, age, health status, etc.) or dog caregivers. Quantitative testing was based on a non-interventional survey study design; thus, tests of sensitivity to change over time and evaluation of clinically meaningful change thresholds were not possible.

6. Conclusions

In conclusion, this study provides evidence in support of the reliability and the content and construct validity for the Canine HRQoL-Q and the HCBQ. As generic measures, the Canine HRQoL-Q and HCBQ can be used to reliably monitor the overall health and well-being of dogs in veterinary practice over time, signal to the veterinarian and caretaker when differences are detected, and promote discussions and decision-making between veterinarian and caretaker. Used together, the two questionnaires provide a comprehensive understanding of factors contributing to the overall health and well-being of dogs.

Future research should be undertaken to determine whether the measures are responsive to change in a longitudinal study and what change in score reflects a meaningful change to veterinarians and canine caretakers. Although these are generic measures of HRQoL and HCB, the measures may

be used as a starting point for the development of questionnaires to assess symptoms of dogs with specific disease conditions.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org. Table S1: Sociodemographic Characteristics of Focus Group Participants Table S2: Sociodemographic Characteristics for Cognitive Interview Participants; Table S3: Sociodemographic Characteristics for Cognitive Interview Participants.

Author Contributions: M.T. developed the statistical analysis plans for Parts 1 and 2 of the study, with critical review and approval by Elodie de Bock and R.L. R.L, P.K., C.O. and A.B. analyzed the data for Part 1 and P.K. and M.T. analyzed Part 2 of the study. All authors critically reviewed and interpreted the results of the analyses. A.B. and M.T. developed the first draft of the manuscript. All authors provided critical feedback, commented on the manuscript and approved the final version. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of Salus IRB (Protocol Number VEAP 7226, approved 09 February 2021).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Relevant data generated during the tool development phase is included in this article. The scoring algorithm is not presented here to preserve intellectual property rights.

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