Supplemental materials for


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Supplemental Appendix

Consensus Reporting Items for Studies in Primary Care (CRISP) Explanation and Examples Guide

Introduction

The CRISP Statement summarizes the rationale, need, underlying research, and development methods of the CRISP Checklist. This appendix details each CRISP Checklist item and provides explanations and examples. This material is based on the findings of previous CRISP studies and reflects the needs expressed by the international, interprofessional, interdisciplinary primary care (PC) community.¹⁻⁵

Checklist items
The CRISP Checklist is displayed in Figure 1 of the CRISP Statement, summarizing essential reporting items for the validity, quality, and usefulness of PC research reports. The checklist is an aid to researchers, authors, reviewers, and editors to help produce high-quality reports of PC research to meet the needs of the diverse PC community.

**Explanation and Examples**

For each reporting item, we explain the rationale for including the item in reports of PC research. Explanations are built upon the data collected from survey participants and the Delphi study panel.\(^1\,^3\,^4\) For each item, we provide examples to illustrate how authors might include the requested information in their report. We prepared original text, rather than quoting published material, to provide suggestions for various methods across a wide variety of research. These examples do not refer to actual publications, data, research tools, or studies. The CRISP Pilot Test\(^6\) included reviews and trial use of these explanations and examples (unpublished data).

Primary care research involves a wide variety of methods, study designs, topics, and settings. Thus, not all CRISP items may apply to all research studies. For example, some items related to quantitative research may not be relevant to a qualitative study. Also, items may be relevant, but the information may not be available due to study design, data availability, or other practical reasons. The absence of such information in a report would be noted on the CRISP Checklist and considered for discussion in the study report.
Other reporting guidelines may also apply to PC research when the study involves specific methods, topics, or research settings.

Some CRISP Checklist items may overlap with items in other guidelines. In crafting their reports, authors would follow both CRISP and methods-specific guidelines to include methods details and the information needed by the PC community. Other major research reporting guidelines relevant to PC research with potential overlap in the requested information are listed in Table A1.

**CRISP Checklist Items**

**Item 1:** Include “primary care” and/or discipline-specific terms in the title, abstract, and/or keywords.

**Explanation:** Primary care possesses unique perspectives on patient care, clinician roles, health service organization, and research.\(^5,6\)

Readers need to be able to identify studies relevant to PC when searching bibliographic databases, scanning tables of contents, and reading abstracts. Indexers (both human and artificial intelligence) need to identify PC research and correctly tag reports.

**Examples:**

A. Title: Trial of amoxicillin for otitis media in children 1-5 years old in general practice.

B. Title: Attitudes toward telemedicine among primary care nurse practitioners.

C. Title: Accuracy of chest radiograph interpretation by family physicians.

D. Appropriate MeSH keywords include, but are not limited to, family nurse practitioners, family physicians, family practice, general practice, general practitioners, primary care, primary care physicians, primary health care, and primary healthcare.
2. DESCRIBE THE STUDY RATIONALE AND IMPORTANCE FOR PRIMARY CARE.

Item 2a: Explain the rationale for the research question and how it relates to primary care.

Explanation: Explicitly stating why the study team chose the research topic helps set reader expectations and provides the rationale for the research question. PC research readers focus on the specific relevance for PC.

Examples:
A. Diabetes is a highly prevalent condition, accounting for 18% of all new patient encounters in PC.
B. Rural workforce shortages have been an ongoing problem for PC practice.
C. Acute myocardial infarction is a serious cause of chest pain and must be considered in patients presenting with undifferentiated chest pain in PC.

Item 2b: Describe the importance or relevance of the topic under study in the primary care setting.

Explanation: To assess the importance of the research topic for PC patients, populations, and healthcare systems, readers need information on the incidence, prevalence, and burden of illness, specifically within PC settings.

Examples:
A. Acute low back pain is the Xth most common reason for new visits to family physicians in the USA.
B. XX% of adults aged 50 years and above seen in PC internal medicine practices in 2020 had been diagnosed with hypertension.

C. Over XX% of all teens who died by suicide were seen by PC clinicians in the two weeks before death.

**Item 2c:** Identify any theory, model, or framework used and explain why it is appropriate to the research question in primary care.

**Explanation:** Theories, models, or frameworks that inform research are often poorly reported. PC research employs a variety of research traditions and methods, which makes explicit reference to the study’s theoretical foundation particularly important for the diverse group of PC readers. This information helps readers understand the choice of study design, methods, analysis, and interpretation.

**Examples:**

A. We used the Consolidated Framework of Implementation Research to inform the interview guide. CFIR encompasses both the inner and outer setting and is particularly relevant as we are interested in how PC policy affects clinical practice.

B. Intersectionality theory allows us to explore family planning services in the context of the whole-person approach of PC

C. Complexity theory enriches our analysis of the transformation of primary care practices into patient-centered medical homes.

3. **DESCRIBE THE RESEARCH TEAM’S PRIMARY CARE EXPERIENCE AND COLLABORATION**

**Item 3a:** Describe the research team’s expertise and experience in primary care practice and/or research.
Explanation: Colleagues from various professions, disciplines, and backgrounds contribute to PC studies. All expertise and perspectives are welcome, but research teams need direct expertise related to PC. This information helps readers understand the researchers' perspectives, competencies, and possible biases.

Examples:

A. The research team included a cultural anthropologist (AA) with experience in the observation of PC clinicians, two experienced general practitioners (BB, CC), a biostatistician (DD), a final-year medical student (EE), and the nurse study coordinator (FF).

B. The study team included ten experienced PC practitioner members of the ABCD practice-based research group, a university-based cardiology consultant, a research epidemiologist, and two PC practice transformation coaches.

C. All members of the case review panel were mental health professionals with two or more years of experience practicing in PC clinic teams.

D. The biostatistician on our team has more than a decade of experience in primary care research. No other members have previously worked on research in primary care.

Item 3b: Describe whether and how primary care patients, practicing clinicians, community members, or other stakeholders were involved in the research process.
**Explanation:** Patient-centered, community-oriented PC values the early, authentic, and ongoing involvement of patients, families, and communities. These partners contribute critical perspectives, valuable expertise, and the lived experience of illness and care. Readers need to know how these voices were engaged throughout the course of the research, from the choice of the research question through to the discussion of the study findings/results.\(^8\)

**Examples:**

A. Our project team included a panel of patients and community leaders who consulted with the study team throughout the study, identifying teen drug use as a community priority, testing the cultural appropriateness of the educational materials, recruiting community education sites, and discussing study findings/results and implications.

B. The author group includes health center team members: patient representative (initials), health education professional (initials), and nurse practitioner (initials).

C. Our work was informed throughout the study by a Community Advisory Group of volunteers selected from community health, educational, and faith organizations. See acknowledgments for names.

D. A community advisory group that provided input into the type of data collected in the original large dataset that we used for this secondary analysis.

4. **DESCRIBE THE STUDY PARTICIPANTS AND POPULATIONS IN THE CONTEXT OF PRIMARY CARE.**
Item 4a: Use person-focused language to refer to the research populations and participants, or use terms based on patient preferences.

Explanation:
Inclusive language acknowledges diversity, conveys respect for all people, is sensitive to differences, and promotes equity.\textsuperscript{9,10,11} Person-first language is often preferred (e.g., person with autism). Identity-first language that respectfully acknowledges that a condition is entwined with a person's identity (e.g., autistic person) is preferred by some groups.\textsuperscript{[ref]} If possible, use the language preferred by the relevant individuals or group.

Examples:
A. Patient representatives reported that members of their community preferred to be referred to as "people living with HIV."

B. The sample included adult patients living with obesity.

C. We identified the patients living with diabetes, depression, and substance use disorders.

Item 4b: If reporting personal characteristics of participants, report the source of the data, the rationale for using it, and the rationale for any classifications used.

Explanation: Race, ethnicity, gender, and other demographic categories are socially constructed and often poorly defined and not accurately recorded.\textsuperscript{12} The decision to collect and report these data can reflect unjustified assumptions and biases. Research design
and reporting should provide the rationale for collecting these data in the context of the study; report the source of the data and classification; provide clear definitions for categories and their sources; and seek accuracy, precision, inclusion, and equity.

**Examples:**

A. Race was self-reported by study participants, and investigators defined race categories based on the updated guidance on the reporting of race and ethnicity in medical and science journals, JAMA 2021.

B. Reporting race and ethnicity in this study was mandated by the US National Institutes of Health (NIH).

C. Data on patient sex was drawn from the original database, based on patient questionnaires that forced a binary choice between male and female and did not collect data on gender.

**Item 4c:** Describe the participants and populations in sufficient detail to allow comparison to other primary care patient populations.

**Explanation:** The variety of PC readers necessitates descriptive data across several dimensions to assess how the study population is similar to and different than the population of patients in their own clinical settings. PC clinicians must apply research findings/results to individual patients and their practice communities. Descriptors should include characteristics known or suspected to be relevant to the problems and outcomes under study.

**Examples:**

A. Relevant data include demographics, vital statistics, multimorbidities, social determinants of health, inequities, etc.
B. The sample included 20 adult patients with ages ranging from 21-35 years. About half (47%) of the sample was unemployed, and all described at least one co-morbidity.

C. The 300 participants were all patients aged 21-75 years at a Federally Qualified Health Center located in an economically disadvantaged community identified as a health workforce shortage area. Patients had high rates of smoking, alcohol, and other substance use disorders and were diagnosed with hypertension, diabetes, obesity, and depression. See Table 1 for data on demographic, socioeconomic, and health status.

**Item: 4d:** Specify if participants have pre-existing therapeutic relationships with the clinical team or are new patients.

**Explanation:** The clinician-patient relationship is a foundation of PC and can influence communication, diagnosis, trust, adherence, and treatment effectiveness. Readers need to know if patient encounters involve established relationships or are with new clinicians/teams.

**Examples:**

A. Study inclusion criteria required two or more previous visits to the clinic team within the previous two years for hypertension.

B. Of the XX patient visits for headache, YY were by patients making their first visit to the PC team.

C. Patients reported if the study visit was with their usual doctor. ("Do you consider this clinician to be your usual source of medical care?")
5. DESCRIBE THE CONDITIONS UNDER STUDY IN THE CONTEXT OF PRIMARY CARE.

Item 5a: Describe if the condition under study is acute or chronic.

Explanation: Primary care includes the management of both acute and chronic conditions. Study reports should define and differentiate acute and chronic conditions, citing any relevant disease-specific criteria.

Examples:

A. Patient inclusion criteria were a) current drug treatment for diagnosis of essential hypertension, b) established patient for at least 12 months prior to the index visit, and ....

B. To be included in the study, patients needed to be adult women aged 18–75 years with a new diagnosis of uncomplicated lower urinary tract infection, no history of UTI in the past year, and no antibiotic treatment for any reason in the previous three months.

C. Diagnosis of chronic low back pain followed the XYZ criteria.

Item 5b: Report how multimorbidity is considered and how it might affect the interpretation of the study findings/results.

Explanation: Primary care involves whole-person care across problems and over time. Much research uses restrictive exclusion criteria that select a sample that bears little resemblance to real-life PC patients.5,6 To reflect PC practice, research should describe
multimorbidity in study participants and address it in the analysis. The absence of co-morbidity can be discussed as a study limitation.

Examples:

A. In this study of patients with diabetes, all had at least one co-morbidity, most commonly hypertension, heart failure, or COPD. We did not explore whether the observed limitations of activities of daily living were due to their diabetes or their co-morbid conditions.

B. This sample excluded patients with a mental health diagnosis, a life-limiting illness, or any plans for pregnancy. Thus, these findings may not apply to patients with multiple or acute mental health conditions.

6. DESCRIBE THE CLINICAL ENCOUNTER UNDER STUDY IN THE CONTEXT OF PRIMARY CARE.

Item 6a: Specify if the study focus is an isolated clinical encounter or a longitudinal course of care. If it is an isolated clinical encounter, specify if it is the first visit or a follow-up visit for the condition under study.

Explanation: Primary care clinicians provide longitudinal care for patients across acute, recurrent, and chronic illnesses. It is important to define if the object of study is a single clinical encounter, a linked series of clinical encounters for the same illness (episode of care or episode of illness). It is important to distinguish the first encounter for a clinical problem from subsequent follow-up encounters. If this information is not available in a PC study, it should be noted as a study limitation.

Examples:
A. We extracted data from the record of the first antenatal visit for study participants who were established patients with two or more clinic visits over the prior year.

B. We were interested in the patient journey for people living with migraine. We included in the analysis data from all initial and follow-up visits over the year from the patient's first visit for any complaint of headache.

C. We examined the first visit for patients presenting with headaches between X and Y dates.

D. This large dataset of primary care visits gives each patient a unique identifier so that we are able to analyze longitudinal patient journeys.

7. DESCRIBE THE PATIENT CARE TEAM.

Item 7a: If care is delivered by teams, describe the team members and their roles.

Explanation: Primary care is often delivered by teams that include a variety of clinicians, other health professionals, and healthcare workers. The mix of professionals, their qualifications, and their patterns of working together may be important influences on the care delivered and the results achieved. This information is also important to the reader seeking to apply the research or compare it to their own setting.

Examples:
A. The study practice consisted of three PC teams, each comprising three PC physicians (family physicians, general pediatricians, general internists), one nurse practitioner or physician assistant, one registered nurse, and three registered medical assistants. The three teams shared one MSW social worker. Patients identified with and received almost all of their PC services within the team. The teams worked closely with a dentist, a diabetes educator, and a substance abuse counselor shared with other teams. All were located in the same facility and shared the electronic medical record. The physicians shared after-hours calls on nights and weekends.

B. Counselling services were provided by master's-level mental health professionals working in the PC clinics with shared electronic health records and opportunities for "warm handoffs" between clinicians.

C. Each clinical team comprised one or more general practitioners and practice nurses, any of whom identified patients who smoked and directed them to the online smoking cessation program.

**Item 7b:** For each clinician category, report profession, specialty, and qualifications.

**Explanation:** Primary care clinicians are a diverse mix of professions, specialties, and disciplines, with varying training and qualification. Also, different healthcare systems use different labels to describe clinicians. Readers need details on profession, degrees, certification, licensure, and years of training to understand who is being studied or providing care. It is insufficient to
aggregate an undefined mix of physicians as "primary care providers." When separate reporting is not possible, this should be noted as a study limitation.

**Examples:**

A. Study GPs were all fellows with the Royal Australian College of General Practitioners.

B. The nurse practitioners had master's degrees in a PC field.

C. The lay assistants were all medical students in the third year of their undergraduate degree.

D. Mental health professionals in the study practices included masters-level counselors and social workers and PhD licensed clinical psychologists.

E. The internists were all board-certified in internal medicine, with no self-reported subspecialty area, with or without self-designation as practicing primary care internal medicine.

F. To be eligible for inclusion in this dataset, the nurse practitioner must be registered in their local region and hold a postgraduate PC qualification.

8. **DESCRIBE THE STUDY INTERVENTIONS IN THE CONTEXT OF PRIMARY CARE.**

*Item 8a:* Describe interventions and their implementation in sufficient detail to enable the reader to assess applicability in their own setting.
**Explanation:** PC is practiced in a wide variety of clinical settings, each with its own mix of people, resources, and constraints. Readers need information on resources required, including time, people, facilities, equipment, sustainability, challenges faced, and solutions adopted.

Readers need sufficient details to assess how new interventions might be implemented and sustained in their own settings and/or to compare the research to their own current practice.

**Examples:**

A. The nurse used their own consulting room with access to the shared medical record. Each consultation took approximately 30 minutes, and then the patient saw the dietitian for an additional 20 minutes at the same visit.

B. The program required intensive follow-up, with all patients called three days prior and again on the day of the appointment. The practice manager phoned all patients who did not attend.

C. The high frequency of dietitian visits with "warm hand-offs" implies that an on-site dietitian would be desirable.

**Item 8b:** Describe any clustering or grouping of patients, participants, clinicians, teams, or practices and how it was addressed in the analysis.

**Explanation:** Primary care data may be collected from multiple patients, clinicians, practices, networks, or other groupings that create clustering effects in the data where within-cluster variation may be less than between-cluster variation. Statistical methods
often assume that observations are random, and clustered data may require analytic techniques to avoid overestimating observed associations.\textsuperscript{14} For qualitative studies, it is also important to consider how participants were grouped and how this might affect the analysis.

\textit{Examples:}

A. The 1000 patients were seen by 100 clinicians (patients/clinician - median 10, range of 2-40) who practiced in 15 separate clinical sites (clinicians/site - median 6, range of 1-20). (See Table 2 for details)

B. We randomized clinical practice sites to receive the team educational intervention or the control printed brochure, and the unit of analysis was the clinical practice site.

C. Analysis was performed at the practice level, accounting for the clustered design using GEE.

D. Interviews were conducted with family doctors and practice nurses. Unfortunately, despite our best efforts, we could only recruit two nurses and combined the nurse and physician interview data. Thus, the primary care nursing voice may be underrepresented in our findings.

E. Each focus group included physicians and social workers, which may have constrained participants' comments about the other group of professionals.

\textit{Item 8c:} Describe the healthcare system in sufficient detail to allow comparisons to other systems.
Explanation: Primary care is the foundation of healthcare but is embedded in complex systems that vary widely between nations and over time. Readers need context to compare their practice setting and system with where the research was conducted. This information could be provided by citation to an appropriate publication or in an appendix. There should be enough detail for a reader unfamiliar with the researchers' setting to understand how system issues affected the intervention and research.

Examples:

A. The nation's system of universal healthcare means that the federal government underwrites costs of patient visits to family doctors.

B. Prescription drugs require a co-payment of up to $50 that is means-tested based on the patient's income.

C. All access to tertiary care requires a referral from a primary care doctor or nurse practitioner.

D. Examples of items to include are access to care, organization of PC, patient registration with GPs, payment system, universal care or coverage, is access to consultant care through PC, payment for medicines and technology, including electronic health records.

9. DESCRIBE STUDY MEASURES USED AND THEIR RELEVANCE TO PRIMARY CARE.

Item 9a: Report if study measurement tools have been validated in primary care populations or settings.

Explanation: The presentation, natural history, and management of patient problems in PC may differ from other patient populations and care settings. Therefore, measures developed and validated in other settings may not be valid for use in PC.
research. Ideally, measures would be validated in PC settings. When such measures are not available, other appropriate measures can be used with this limitation mentioned in the discussion.

**Examples:**

A. We assessed low back pain functional outcomes with the XYZ scale, which was derived in general practice and has been used in multiple large-scale studies, including in PC settings.

B. We applied the diagnostic criteria for XYZ, commonly used in patient care and research across outpatient care settings, including PC.

C. To measure wound healing, we used the ABC index, initially developed in outpatient diabetes clinics and broadly used in PC studies, though never formally validated in the PC setting.

**Item 9b:** Describe how the measurement tools used are meaningful to primary care patients and their care.

**Explanation:** Clinically meaningful changes in patient-oriented outcomes are more important than statistically significant changes in intermediate outcomes. Patient preferences can guide the selection of study outcomes and interpretation of research findings/results. The perspectives of PC patients and clinicians may be different than in other research settings.\(^4\)\(^-\)\(^6\)

**Examples:**
A. Patient preference research has established the importance of reducing the unnecessary use of antibiotics in treating children with respiratory illnesses in PC.

B. A reduction of four points on the XYZ scale is considered a clinically meaningful improvement among PC patients with low back pain.

C. Smoking cessation reduces morbidity and mortality from major chronic illnesses in PC.

**Item 9c:** Report findings/results in forms that are clinically interpretable by primary care clinicians and patients.

**Explanation:** Clinicians and patients need study results reported in ways they can easily apply to understanding risks and benefits and making personal decisions, in addition to standard statistical reporting.¹⁶

**Examples:**

A. NNT - number needed to treat - is useful to some clinicians and can be calculated from the Absolute Risk Reduction and event rates.

B. Report both absolute and relative risk with 95% Confidence Intervals for each.

C. We found that graphical representation of these risks helped clinicians and patients make decisions. See the example....

**10. DISCUSS THE MEANING OF STUDY FINDINGS/RESULTS IN THE CONTEXT OF PRIMARY CARE.**
**Item 10a:** Discuss implications of the study findings/results for research, patient care, education, and policy with specific focus on primary care.

**Explanation:** Readers need to understand the implications of the research with a specific focus on PC, beyond any implications for medical care more generally. While implications of the research are commonplace across research reports, CRISP highlights the need to consider and report on the implications for PC explicitly

**Examples:**

A. These findings suggest that the clinical spectrum of depression seen in PC clinics may differ from patients seen in specialty psychiatry or substance-abuse clinics. Further research on the diagnosis, management, and prognosis of depression in PC may improve care outcomes in those settings where most patients with depression receive their care.

B. Many patients resistant to Covid vaccination consented after discussion with their trusted general practitioners. This suggests that more public education, resources, and support for general practice may be an effective strategy for increasing population vaccination rates.

C. The high prevalence of PTSD symptoms in male veterans in these PC clinics suggests a role for better integration of mental health and PC services.

**Item 10b:** Discuss the implications of study recommendations on demands and priorities in primary care practice.
**Explanation:** Primary care delivers comprehensive care in the context of multiple needs, risks, benefits, and priorities. It often does this complex work with limited time and resources. Adopting new services must balance trade-offs with other proven interventions or service delivery roles.

**Examples:**

A. Most study clinicians agreed that adding this new service into daily practice was possible and would fit within their daily workflows.

B. Although we have recommended that more COVID testing be done in PC, this may mean there is less time to devote to other valuable functions, such as screening or behaviour change counseling.

C. Insisting on weighing patients at every visit may make some patients hesitant to present for care. It also takes the practice nurse away from other tasks.

**Item 10c:** Comment on any research processes that might influence the applicability of the study findings/results in diverse primary care settings.

**Explanation:** Research processes can influence study results, making it difficult to achieve similar study outcomes in real-world settings. These may include recruitment, incentives, implementation, extra clinical services, and other study supports not routinely
available in practice. Readers need details on problems encountered and adaptations made in the research setting. Include a discussion of the effects of the research processes on study findings/results and applicability in real-world practice settings.

**Examples:**

A. We offered patients an honorarium for every consultation they attended, which may have increased attendance rates and contributed to program success.

B. Patients in this trial were provided medication free of charge and dispensed at the point of consultation, which may have increased patient adherence rate. Experience in practices without these services may be different.

C. All patients were phoned every three weeks to ask how they were finding the new program. Most patients said that they enjoyed the phone call with the research nurse and that it helped them stay on the program, which may have ramifications for real-world implementation.

D. Clinicians were required to enter study data in addition to routine clinical data. They complained about this extra work and reported that it reduced the time available for patient care. In real-world practice, they would not have this burden of double data entry, which could increase the time available for handovers between medical and mental health clinicians.

E. All visits to the PC team usually require a fee, but the research program covered this.

**Discussion**
The appropriateness of these checklist items is supported by the strengths of the CRISP program of research and development: rigorous, prospective, transparent, and inclusive. Each item is on this list because the PC community feels it is necessary to empower their use of published research. Each item offers an opportunity to increase the application of research findings to inform practice, improve patient care, and promote population health.

Some CRISP Checklist items may not often appear in currently published research reports. Our early studies documented deficiencies in current reports of PC research,¹,²,³ and the CRISP Statement attempts to address these opportunities for improvement. Some checklist items may seem more aspirational than essential. Our goal was to meet the needs of research producers and users, not just the requirements of a specific research methodology.

The effectiveness of the CRISP Checklist in improving PC research reports and the implementation of their findings deserves formal trials. We expect CRISP to be a living document that responds to the best evidence and adapts to the changing needs and opportunities in PC research and practice.
REFERENCES – APPENDIX


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In addition to CRISP, authors should use other guidelines relevant to their studies.

Some CRISP reporting items may overlap with items in these or other guidelines.
Many research reporting guidelines also have extensions that address specific methods, topics, and populations.

For more information on these and other research reporting guidelines, see the EQUATOR Network: https://www.equator-network.org