Development and Content Validation of a Patient-Reported Sexual Risk Measure for Use in Primary Care

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BACKGROUND: Patient-provider sexual risk behavior discussions occur infrequently but may be facilitated by high-quality sexual risk screening tools.

OBJECTIVE: To develop the Sexual Risk Behavior Inventory (SRBI), a brief computer-administered patient-reported measure.

DESIGN: Qualitative item development/quantitative instrument validation.

PARTICIPANTS: We developed SRBI items based on patient interviews ($n = 128$) at four geographically diverse US primary care clinics. Patients were diverse in gender identity, sex, sexual orientation, age, race/ethnicity, and HIV status. We compared sexual risk behavior identified by the SRBI and the Risk Assessment Battery (RAB) among patients ($n = 422$).

APPROACH: We constructed an item pool based on validated measures of sexual risk, developed an in-depth interview guide based on pool content, and used interviews to elicit new sexual risk concepts. We coded concepts, matched them to item pool content, and developed new content where needed. A provider team evaluated item clinical relevance. We conducted cognitive interviews to assess item comprehensibility. We administered the SRBI and the RAB to patients.

KEY RESULTS: Common, clinically relevant concepts in the SRBI included number of sex partners; partner HIV status; partner use of antiretroviral medication (ART)/pre-exposure prophylaxis (PrEP); and recent sex without barrier protection, direction of anal sex, and concern regarding HIV/STI exposure. While 90% reported inconsistent condom use on the RAB, same-day SRBI administration revealed that for over one third, all their partners were on ART/PrEP.

CONCLUSION: The SRBI is a brief, skip-patterned, clinically relevant measure that ascertains sexual risk behavior across sex, sexual orientation, gender identity, partner HIV serostatus, and partner treatment status, furnishing providers with context to determine gradations of risk for HIV/STI.

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INTRODUCTION

Despite rising rates of sexually transmitted infections (STI) in the USA,[1] sexual risk behavior (SRB) is under-addressed in clinical care,[2–5] including among higher-risk populations, such as men who have sex with men (MSM),[6] and patients in HIV care[4,7–10] including methamphetamine users.[8] Reasons include time constraints, provider discomfort discussing the topic, and inaccurate risk perception.[3–5,11–16]

Computer-administered clinical assessments that include patient-reported SRB may decrease some of these barriers by identifying those with SRB and minimizing social desirability bias.[17–20] Clinical assessments of patient-reported outcomes and measures (PROs) have been well-tolerated among patients and useful to providers.[21–24] We have shown that delivering same-day clinical assessment PRO results to providers at the point of care can change provider awareness and/or actions for domains such as depression, substance use, and antiretroviral (ART) medication adherence.[25] In that same study, we found that SRB assessment with a legacy scale, an adaptation of the Risk Assessment Battery (RAB),[26,27] did not result in substantial changes in provider care. Further, informal patient and provider feedback suggested that the RAB was lengthy, disliked by patients, and did not yield clinically actionable information.

Measurement of patient-reported SRB lacks a gold standard.[20,28,29] SRB measures are difficult to validate[30] and heterogeneous in response format,[28,31] recall period,[28] and content.[28] Many are population- or project-specific,[29,32] rendering them impractical for routine administration in general primary care. We thus aimed to develop an improved measure to elicit clinically actionable SRB for use in busy clinical care settings.

We developed the Sexual Risk Behavior Inventory (SRBI), a touch-screen-administered measure for use in primary care with patients that is inclusive of diverse gender identities, sexual orientations, and of patient and partner HIV status, employing skip patterns to minimize patient burden. The SRBI identifies behaviors necessary to assess SRB in the absence of barrier protection, including serosorting, anal sex role among MSM, and partner use of ART/pre-exposure prophylaxis (PrEP) medications.

METHODS

Methodological Overview

Figure 1 provides a methodological overview. In concordance with NIH-Patient Reported Outcomes Measurement Information System (PROMIS) recommendations for instrument development,[33] we developed a literature-review-based item pool of legacy SRB items. We categorized similar items, winnowing items within each to the best alternatives. We designed an in-depth interview guide covering content areas. We conducted concept elicitation (CE) interviews with patients, coded transcripts to match item pool content, and identified salient unmatched content requiring new item development. A panel of HIV care providers prioritized candidate items based on clinical relevance. We presented selected items to patients for cognitive interviewing, using their feedback to clarify item language when needed. We administered the resulting SRBI to patients alongside the legacy RAB. Human subject committees at each site approved all research activity.

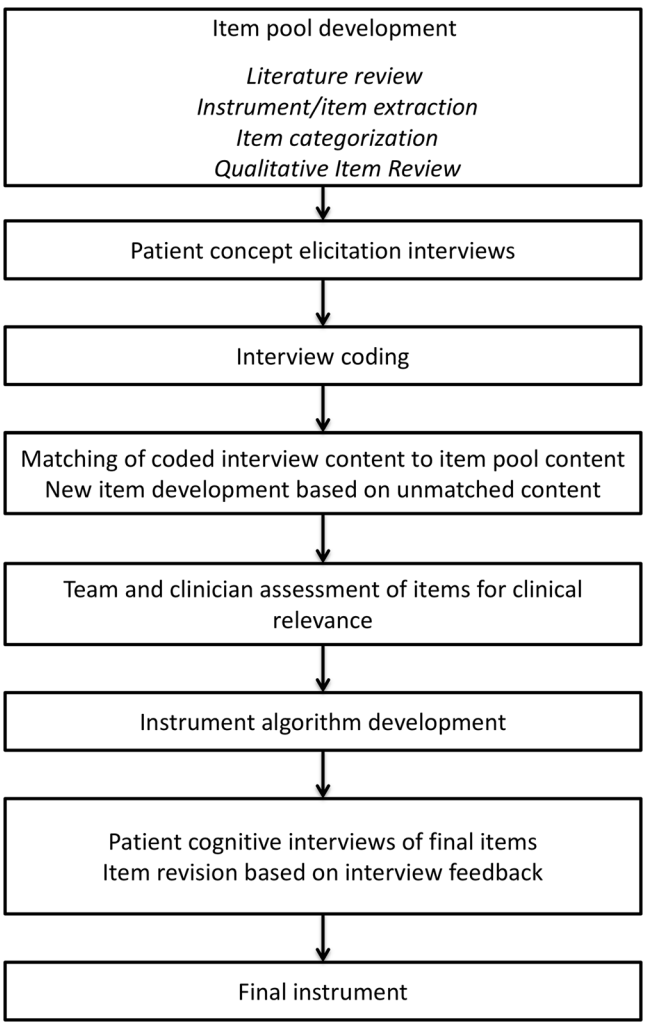

Fig. 1 Methodological overview.

Item Pool Development

We convened a team of clinicians and study investigators to establish a governing concept of SRB; we defined this as "engagement in behavior which exposes one to risk of STIs." We reviewed literature with the assistance of reference librarians using Medline to identify SRB measures developed or used in care since 2003. We included measures of SRB, sex addiction, condom attitudes, condom self-efficacy, and sensation seeking. Our initial search yielded 165 citations. We excluded instruments from population-based surveys not intended for clinical care, instruments not in North American English, instruments requiring interviewer administration, instruments with content outside our governing concept, older versions of since-updated instruments, and instruments unavailable after two attempts to contact authors. This strategy yielded 18 instruments and 273 items.

Item Categorization

Two qualitative researchers independently categorized candidate items using an open-coding process; from this process, the larger qualitative team met to achieve consensus on final fixed codes. We identified four general thematic areas for categorization: generic sexual behavior (e.g., without querying risk or preventive behavior), risk/prevention practices (e.g., condom use or lack thereof), reasons for loss of control (in a sexual situation), and sex in exchange for money/goods/assistance. We further coded items into subgroups termed "factors"; for example, the category of "risk/prevention practices" included items organized by factors of "barrier protection," "discussion with partner," and "avoiding fluid exchange."

Three reviewers with content area expertise independently winnowed items into a smaller pool, selecting the best among alternatives with similar content, using the PROMIS Qualitative Item Review (QIR) process.[34] We reconciled discordance through group discussion, resulting in a pool of 85 distinct candidate items.

Concept Elicitation Interviews

We used content areas from these items to develop an interview guide that elicited concepts of patient SRB. We consulted content area experts to maximize relevance across sexual orientation and gender identity.

We invited patients for hour-long interviews, offering $25 compensation. We presented patients with items from the modified RAB that assessed frequency of condom use.[35] We invited patients to provide comment/critique on the items; this familiarized patients with typical domain content. We asked patients what they understood about HIV/STI transmission and prevention, and explored attitudes about "risky" versus "safe" sex, before querying their own sexual behaviors. Typical prompts included what behaviors they had heard put individuals at risk for contracting HIV, whether and which sexual behavior(s) are relevant for discussions with providers, past experiences attempting to reduce HIV/STI transmission risk, and perceived situations in which avoiding risky sexual behavior could be difficult.

Study Population and Recruitment

We approached patients living with and without HIV at four US clinics within the Centers for AIDS Research Network of Integrated Clinical Systems (CNICS): Fenway Community Health (Boston, MA), 1917 Clinic (University of Alabama-Birmingham), Owen Clinic (University of California-San Diego), and Madison Clinic (Harborview Medical Center/University of Washington-Seattle). Patients at these clinics complete PRO assessments on touch-screen tablets before visits. The PRO assessment included items that determined study eligibility. We recruited patients living with HIV (PLWH) in person before or after a clinic visit. Inclusion criteria were sexually active (anal and/or vaginal) with one or more partners in the past 12 months, women who had sex with women (WSW), and for others, condom use less than "all the time." We screened HIV-uninfected patients by phone for eligibility. We recruited a convenience sample with heterogeneous numbers of partners and risk levels. We sought to enroll a group with over half of subjects with ≥ two sex partners over the past year. We also sought to enroll a group with heterogeneous HIV/STI exposure risks, based on the model by Murphy et al.[36] We defined those other than WSW who reported using condoms "never" and "some of the time" as a high-risk group, those who reported using condoms "most of the time" as a moderate risk group, and those using condoms "all of the time" as the lowest risk group.

For CE interviews, we sought robust representation of groups at highest risk for HIV/STI: transgender women, cis-gender MSM and/or men who have sex with both men and women (MSMW), and cis-gender women who have sex with men exclusively or who have sex with men and women (WSM/WSMW). We attempted to match interviewer and participant sex to minimize patient discomfort; transgender patients chose the sex of their interviewer. We continued enrollment until reaching concept saturation, meaning that no new themes emerged from additional interview transcripts.

Concept Elicitation Interview Coding, Matching to Legacy Item Themes, and Development of New Content

An independent transcription agency transcribed interviews. A multi-site qualitative research team excerpted potentially relevant interview content, using Dedoose software to apply item pool codes to excerpts. Two team members independently matched coded excerpts to legacy item themes; a third team member led discussions to reconcile discrepancies. We identified excerpts that did not match legacy item content as themes for potential new item development.

We wrote new items and adapted legacy items to reflect 3-month recall periods, as recommended.[37] We drafted a programmable algorithm using skip patterns based on single versus multiple partners, patient sex, partner gender identity, and patient/partner HIV serostatus (concordant vs. discordant). For example, MSM indicating sex exclusively with cis-gender males do not receive items regarding vaginal sex; PLWH reporting a single HIV-uninfected partner receive a partner pre-exposure prophylaxis (PrEP) use item; and so forth. We drafted items to approximate a sixth grade or lower English literacy level.

Team and Clinician Review

HIV care providers, co-investigators, and the qualitative team reviewed the drafted measure and assessed the frequency of SRB concepts from the qualitative data and the clinical relevance of each concept, defined as information likely to initiate/change a provider's actions.

Cognitive Interview Testing

We tested the resulting items for comprehensibility, using the same recruitment criteria used for CE interviews. We showed patients items relevant to their sex, partner gender identity, and partner HIV status. Interviews were ~45 min in length; participants received $15 compensation. We calculated the number of patients that comprehended each item. We reviewed less-than-unanimously understood items for opportunities to clarify. We conducted interviews until reaching concept saturation.

Development of SRBI

We used all of these data elements to compose the final version of the SRBI. The instrument shows patients approximately 12 items, skip-patterned depending on behaviors (see Fig. 2).

Comparison with the RAB

We administered the SRBI via touch screen tablet to PLWH who completed the RAB the same day as part of routine clinic PRO collection and continued recruiting a convenience sample of patients living with and without HIV until achieving

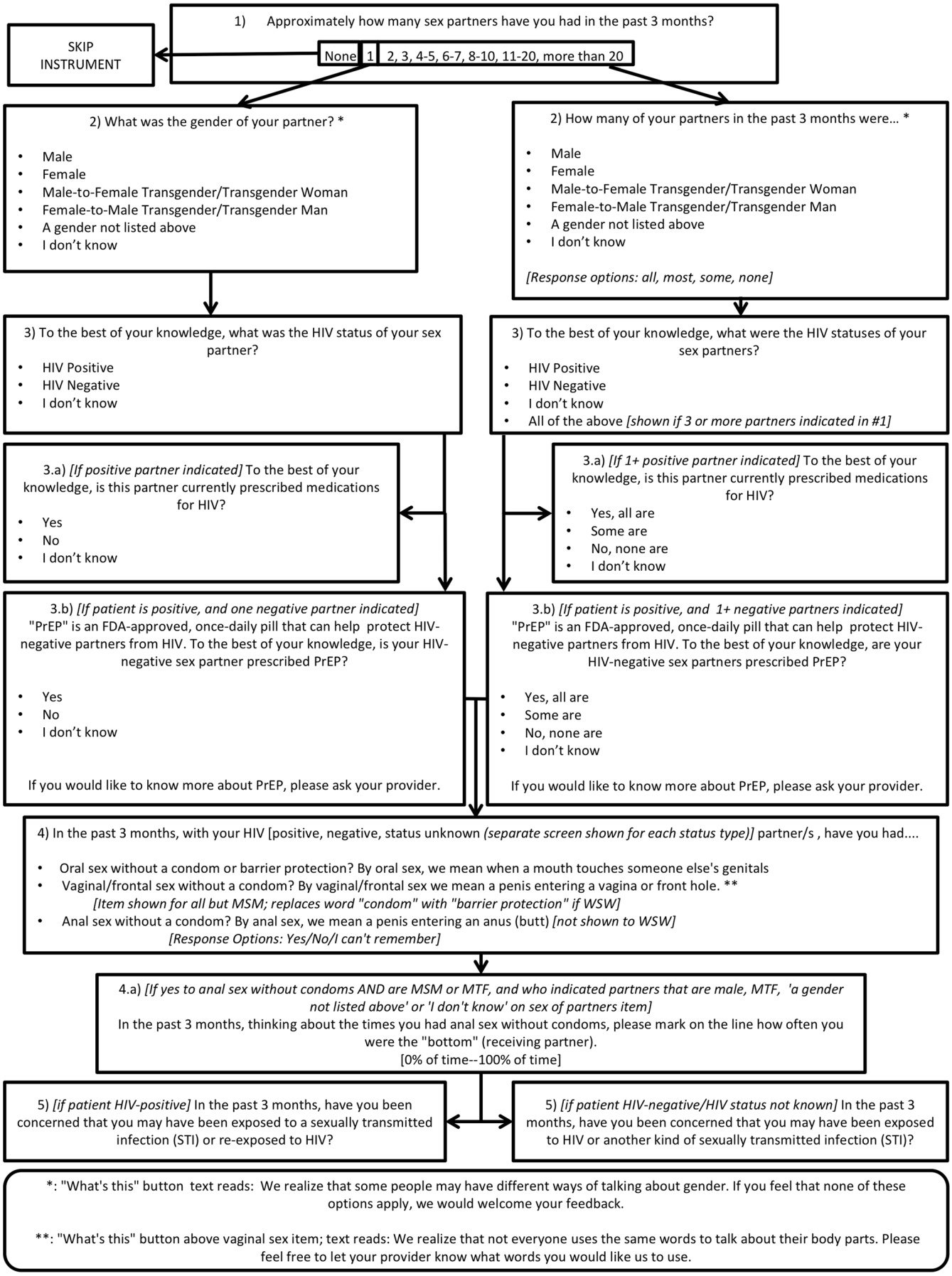

Fig. 2 Sexual Risk Behavior Inventory.

robust numbers of high-, medium-, and low-risk patients. Patients received $25 for completing the additional measures.

RESULTS

Concept Elicitation and Matching to Legacy Scale Themes

Demographic and clinical characteristics of CE interview participants ($n = 91$) are shown in Table 1.

We matched ~400 interview excerpts to legacy items, including the following concepts: number of sex partners; context of meeting sex partners (i.e., smartphone apps, websites); partner HIV/STI status; partner ART/PrEP status; partner HIV viral load; nature of partnership (i.e., long-term vs. anonymous); oral, anal, and vaginal sex behavior; condom use; sex addiction; sexual remorse; HIV/STI disclosure; sexual satisfaction; direction of anal sex; and concern regarding HIV/STI exposure. Concepts found in the interviews but not the item pool included partner serosorting, perceptions of partner fidelity, reasons for unsafe sex, concurrent sex partners, and group sex. The category "reasons for unsafe sex" had many matched and unmatched concepts, including having a low viral load, taking PrEP, low perceived HIV/STI risk, pregnancy goals, special occasions (i.e., anniversary), dislike/trouble using condoms, substance use, deference to partner's wishes, forced sex, loneliness, sadness/depression, and ambivalence. We drafted the most common concepts as potential items.

Results of Team and Provider Meetings

Providers ($n = 7$) found that several concepts lacked clinical relevance, including frequency of sex *with* barrier/condom protection, and direction of oral sex. Providers deemed overall number of partners and context of barrier protection (i.e., HIV status of partner) to be clinically relevant. We judged language querying "partner type," such as "casual," "primary," "steady," and "main," potentially confusing and more clearly elicited during direct patient-provider conversation. Similarly, we found a lengthy list of reasons for unsafe sex to be a poor fit for self-administration.

Results of Cognitive Interview Testing

Cognitive interview participants ($n = 37$) found the terms oral, vaginal, and anal sex confusing. We added clarifying statements such as "By oral sex, we mean when a mouth touches someone else's genitals." Several interview participants did not understand what was meant by the term "gender identity"; several were unfamiliar with PrEP. To address these concerns, we added clickable "what's this?" buttons that provide clarifying text. Transgender patients suggested addition of the term "front hole" alongside "vagina" to increase relevance to transgender women. Interview participants strongly favored the word "gender" to "sex."

Table 1 Demographics Across Activity Type

	Concept elicitation	Cognitive interviews	Crosswalk
Total	91	37	422
HIV serostatus			
HIV+	67 (74%)	32 (86%)	375 (89%)
HIV−	24 (26%)	5 (14%)	47 (11%)
Present sex			
Male	53 (58%)	22 (59%)	351 (83%)
Female	28 (31%)	12 (32%)	67 (16%)
MTF transgender	7 (8%)	3 (8%)	3 (1%)
FTM transgender	3 (3%)	0 (0%)	1 (<1%)
Race			
African-American	31 (34%)	10 (27%)	110 (26%)
White	50 (55%)	25 (68%)	281 (67%)
Asian-American, Hawaiian, Pacific Islander	3 (3%)	2 (5%)	7 (2%)
Native American	0 (0%)	0 (0%)	2 (<1%)
More than one race or other race	7 (8%)	0 (0%)	7 (2%)
Not reported	0 (0%)	0 (0%)	15 (4%)
Latino/Hispanic, any race	8 (9%)	5 (14%)	70 (17%)
Age			
<30	24 (26%)	13 (35%)	68 (16%)
30–39	20 (22%)	10 (27%)	128 (30%)
40–49	24 (26%)	8 (22%)	125 (30%)
50+	23 (25%)	6 (16%)	101 (24%)
Sexual orientation, by behavior[a]			
MSM[b]	44 (48%)	19 (51%)	297 (70%)
MSMW	10 (11%)	5 (14%)	9 (2%)
MSW[b]	22 (24%)	8 (22%)	62 (15%)
WSM[c]	35 (38%)	15 (41%)	63 (15%)
WSMW	9 (10%)	3 (8%)	1 (<1%)
WSW[c]	9 (10%)	3 (8%)	8 (2%)
Sexual risk level[d]			
High	26 (29%)	13 (35%)	278 (66%)
Moderate	34 (37%)	19 (51%)	88 (21%)
Low	31 (34%)	5 (14%)	56 (13%)
HIV+ only			
Time since initial HIV diagnosis			
0–5 years	24 (26%)	–	–
6–10 years	15 (16%)	–	–
>10 years	28 (31%)	–	–
Route of transmission			
MSM	34 (37%)	–	238 (63%)
MSM/IV drug use	3 (3%)	–	7 (2%)
IV drug use (non-MSM)	4 (4%)	–	40 (11%)
Heterosexual	19 (21%)	–	78 (21%)
Other/unknown	7 (8%)	–	12 (3%)
Most recent CD4			
0–199	3 (3%)	–	28 (7%)
200–349	5 (5%)	–	46 (12%)
350+	59 (65%)	–	301 (80%)

[a] *Transgender patients represented by sex corresponding to current gender identity*
[b] *Includes men who have sex with men and women*
[c] *Includes women who have sex with women and men*
[d] *High risk = 2+ sex partners in the past 6 months and condom use "never" or "some of the time"*
Moderate risk = 2+ sex partners in past 6 months and condom use "most of the time"
Low risk = condom use "all of the time" with one or more partners
MTF male to female (transgender), FTM female to male (transgender), MSM men who have sex with men, MSMW men who have sex with men and women, MSW men who have sex with women, WSM women who have sex with men, WSMW women who have sex with men and women, WSW women who have sex with women

Resulting Final Measure and Crosswalk Testing

The SRBI algorithm (Fig. 2) incorporates skip patterns and differential wording based on whether a respondent has one or multiple sex partners, sex-based partnership configuration (i.e.,

MSM, WSM), patient/partner HIV status, and endorsement of anal sex without condoms. Same-day administration of the RAB and SRBI ($n = 422$) revealed low levels of consistent condom use (10%) among patients reporting anal or vaginal sex on the RAB. Per the SRBI, of patients reporting condom use "less than all the time" on the RAB, 22% did not know their partner/s HIV status; 16% reported not knowing whether one or more of their partners were prescribed ART/PrEP; 19% reported having no partners prescribed ART/PrEP; 12% reported that some of their partners were prescribed ART/PrEP; and 38% reported that all partners were prescribed ART/PrEP.

DISCUSSION

Despite rising rates of STI in the USA[1] and evidence of less-than-adequate patient-provider discussions of SRB,[2–5,7–10,38] there are rays of hope. Evidence shows patient willingness to discuss SRB with providers[3,39]; that PROs reduce social desirability bias when compared to in-person interview in the area of sexual health[40]; and that discussions of SRB in care lead to additional screening and follow up[41] as well as positive clinical outcomes.[42] Further, as part of the movement toward patient-centered care practices, PROs have become more commonplace,[43] with evidence of successful integration into routine care with results delivered to providers at the point of care.[43,44] These combined factors highlight an opportunity to develop a targeted, brief, clinically relevant measure of SRB that helps initiate such discussions from a better-informed starting point. We designed the SRBI for this context. It uses terms for sex-related behaviors vetted by a diverse group of patients, which may facilitate conversations that could otherwise be uncomfortable. It focuses on SRB, avoiding distinctions that do not impact HIV/STI risk, while identifying specific behaviors—such as partner use of ART/PrEP—that were not addressed by legacy measures.

Concepts of SRB among patients were numerous, diverse, and at times specific to patients' sex, sexual orientation, and HIV status. This presented an opportunity to develop a skip pattern in the SRBI responsive to the modern context of sexual decision-making, to help illuminate patient decisions surrounding HIV/STI risk and prevention. For example, we found patients' decisions regarding whether to engage in condom-less sex to be heavily informed not only by knowledge or perception of one's own versus a partner's HIV status but also by use of ART, detectability of one's own/partner viral load, and, for MSM, positioning choice for anal intercourse. Such strategies have been noted elsewhere.[45–48] Use of PrEP, known to be highly effective against HIV transmission,[49–51] may also influence condom use. While condom use remains the gold standard beyond abstinence for HIV/STI protection, interviews suggested that assessment of condom use without accounting for these factors would be less informative of true risk behavior in the current ART era. Clearly, a patient-provider conversation about condom-less sex would differ in approach and content with, for example, a virally suppressed patient reporting one mutually monogamous, long-term, PrEP-adherent partner, than with virally unsuppressed patients not using condoms, or patients reporting condom-less sex with partners of unknown HIV status.

In comparing the RAB and SRBI, we found that simply measuring frequency of condom use in the absence of additional context provided by the SRBI failed to distinguish between high- and low-risk patients, limiting clinical usefulness of the RAB and measures exclusively focused on condom frequency. For example, a large proportion of patients reporting condom-less sex on the RAB (38%) reported that all of their partners were prescribed either ART or PrEP on the SRBI, indicating some level of familiarity with sex partners and an effort to minimize HIV transmission risk. This circumstance contrasts sharply with that of the 22% of patients that did not know their partner/s HIV status. The SRBI stratifies patterns of behavior based on our overarching definition of SRB, relating specifically to risk of HIV/STI transmission.

In selecting items for the final measure, we balanced several factors: degree of clinical relevance, the need for richer contextualization of risk behavior, imagined patient tolerability of items, and the need for brevity. To ensure clinical relevance, we crafted the measure to target current SRB pertinent from a HIV/STI prevention standpoint, excluding assessment of "protected" sex practices and lifetime items frequently found in other SRB measures.[32,35,52] Instead, we query whether or not the patient had sex *without* condoms or barrier protection, in the context of what the patient perceives about their own and partner HIV/STI, ART/PrEP, and viral load status. We also considered the clinical relevance of identifying partnership type, as item pool language referencing it was vague, confusing, and subject to misinterpretation even when defined. Examples of troublesome language are binaries such as "primary/secondary," and terms such as "non-primary," casual, steady, and/or main to describe partners. Few patients interviewed used such language, instead using terms such as "friend," "husband," "girlfriend," "someone I hook up with," or "f–k buddy." Given that none of these terms reliably indicate level of sexual exclusivity, or even familiarity, we deemed partnership type to be both less clinically relevant and more effectively elicited in the context of a patient-provider conversation if needed.

In discussions of patient tolerability of items, the issue arose of how much supporting context warrants inclusion in the measure, and whether that context is best elicited by a PRO measure, versus a face-to-face conversation. While reasons for unsafe sex was considered potentially clinically relevant, the patient burden of reviewing and selecting from a lengthy list of wildly diverse reasons ranging from positive emotional states (i.e., "anniversary") to sexual violence was believed to outweigh any benefit. We concluded that the most clinically relevant "reasons," namely depression, substance use, and sexual violence, were better assessed by other PRO measures, such as the PHQ-9 for depression; others could be more effectively elicited from face-to-face conversations. In this

spirit, we visualized a measure that facilitates, rather than replaces, patient-provider discussion of SRB.

The use of PROs to facilitate SRB discussions bears particular importance for identifying and treating patients that engage in same-sex sexual behavior. Lesbian, gay, bisexual, and transgender patients experience significant health disparities, including increased suicide attempts among youth, HIV/STI risk, and substance use.[53] Providers may often be the only ones with whom patients can disclose and discuss sexual behavior, sexuality, and/or gender identity without negative consequence.[53] Hence, we strongly recommend collection of patient-reported gender identity and sexual orientation to complement assessment of SRB. For all patient populations, same-day, patient-reported SRB measurement may reduce the potential awkwardness of bringing the topic up "cold" or seemingly at random in the context of a time-constrained appointment, generating the possibility of a more honest, well-informed, and targeted discussion. The SRBI in particular offers a clinically relevant, comprehensive yet brief means of assessing SRB, helping providers to distinguish true levels of patient HIV/STI risk by providing fuller context surrounding condom-less sex, and to determine when to test for HIV/STIs. Further validation work should assess the SRBI's predictive value of incident HIV/STI.

LIMITATIONS

This study has a few limitations. First, despite the many concepts elicited from CE interviews, we note that the private nature of SRB could have limited patient discussion. Second, while our patient sample included WSMW, it included few WSW who did not also have sex with men, due to low numbers in our clinic populations. Because of this, the measure may be less relevant or generalizable to lesbian-identified women/WSW who do not have sex with men. Third, the SRBI focuses on sexual risk behavior, and not contextual factors (e.g., substance use, depression, etc.). Those seeking to understand contexts underlying SRB would need to assess these with other instruments. Fourth, we developed the SRBI specifically for electronic administration using skip pattern logic and have no information regarding whether this approach could work as a paper-based assessment. Fifth, we note the need to assess patient satisfaction with the SRBI. Finally, we caution that patient use of ART/PrEP does not reduce non-HIV STI risk; use of the SRBI is meant to inform, not replace, discussion of both HIV and non-HIV STI transmission risk.

STRENGTHS

We recruited a diverse patient population with respect to demographic characteristics, sexual orientation, gender identity, sex of sex partners, and risk levels, which we believe enriched development of the SRBI. In addition, this work drew on the expertise of researchers, many of them HIV care providers.

CONCLUSION

Concept elicitation of sexual risk among HIV-infected and uninfected patients yielded rich, diverse content and underscored the need for a skip-patterned measure of SRB relevant across sex, sexual orientation, gender identity, and partnership configurations that incorporates factors influencing decisions whether or not to use barrier protection in the current era of ART and PrEP. Provider input and patient cognitive interviews furnished development of the SRBI, a brief, clinically relevant, comprehensive, well-tolerated SRB measure that may promote more meaningful discussion of sexual risk in the context of routine clinical care.

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Compliance with Ethical Standards:

Conflict of Interest: *The authors declare that they do not have a conflict of interest.*

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