Inclusion of Patients with Limited English Proficiency (LEP) in Research
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Facilitator:
Dacia Christin (daciac@crab.org)

Aims:
1) To understand disparities in cancer screening and clinical trial recruitment of LEP patients and impact.
2) To recognize language-specific eligibility criteria, with a close exploration of PROs.
3) To develop tools for asking patients to identify race and ethnicity as defined by OMB.

Disparities for patients with limited or no English proficiency (LEP)

Lower rates of cancer screening and access to cancer prevention services:
- Factors include poor access to services, immigration status, insurance coverage, high cost of care, insensitivity to patient needs, lack of interpreter services.

Low rates of inclusion in clinical trials.
- Many LEP patients already have lower rate of medical care seeking behaviors due to barriers.
- Eligibility criteria in many protocols exclude patients with limited English.
- Budget limitations reduce ability to translate consent and other patient-facing materials.
- Are we including all possible patients on our end?

Why is this an issue?
- Impact on generalizability
- Implications for equity and justice
- Exclusion based on language ability should be ethically and/or scientifically justified.

Tips:
- Always aim for inclusion!
- If unsure about eligibility, please verify!

Eligibility criteria in protocols:

Can patients who do not speak English or Spanish proficiently be included in the protocols for the examples below?
1) S1703: "Patients who are able to complete questionnaires in English or Spanish must participate in patient-reported outcome (PRO) assessments as outlined in Section 14.4."

2) S2010: "Participants must be able to complete Patient-Reported Outcome (PRO) instruments in English or Spanish."

What if is there is no mention of language accommodation in the eligibility criteria?
→ Aim for inclusion! If unsure, please check with data coordinator for study in question.

OMB's race and ethnicity reporting

Race and ethnicity are not universal concepts!
- Many countries understand race and ethnicity differently from the US.
- Other issues, some more complex than others. For example, read the OMB definition of "Hispanic': "A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."
    o What should indigenous peoples from Central/South America select?

Why is this information collected?
- Understand generalizability of findings and differing responses to interventions.
- Gain insight into inclusion efforts and recognize when improvement in inclusion efforts is required.
- Allow to draw conclusion or make hypotheses about specific treatments, trends and needs.
- Tailor outreach to specific populations.

Tips:
- Let patients know why this information is collected.
- Let patients know they can select more than one option for race.
- Language like cultural or ancestral heritage may be more helpful to some patients.
- Be aware change is coming (see Wines reference below)!

Some resources for further reading

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5. Loree JM, Anand S, Dasari A, et al. Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals From 2008 to 2018. JAMA Oncol. 2019;5(10):e191870. doi:10.1001/jamaoncol.2019.1870
6. Resnik DB, Jones CW. Research subjects with limited English proficiency: ethical and legal issues. Account Res. 2006 Apr-Jun;13(2):157-77. doi: 10.1080/08989620600654043. PMID: 16830406; PMCID: PMC3942994.
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