A Systematic Review of Clinical Trials Addressing Health Literacy

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Background

- There is a strong need to improve the participation of underrepresented populations in clinical trials.
- Each participant must be fully informed during all phases of clinical research, empowering them to choose participation, understand the potential risks and benefits, and adhere to study protocol.
- The responsibility for health literate communication is with research institutions (academia and pharma, IRBs, investigators and study staff.
- There is a broad need to optimize all patient materials throughout all phases of research, beyond informed consent.

Objective

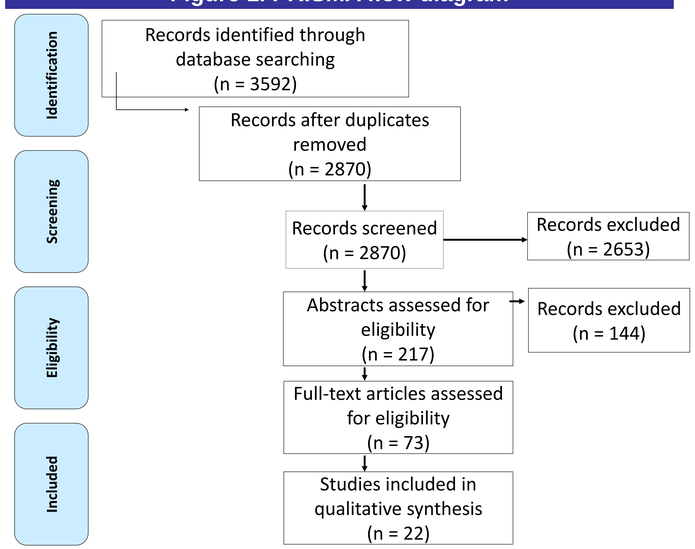
- To conduct a systematic literature review to evaluate health literacy best practices in clinical trials, especially, for underserved populations
- To identify best practices for creating patient-centered clinical trial content

Methods

A systematic literature search following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) method using the following databases:
PubMed, the Cumulative Index to Nursing and Allied Health Literature SCOPUS, Cochrane and Web of Science for English-language articles published from January 2009 through December 2019.

- Studies following a randomized control trial study design and intervention that measured health literacy selected
- Two researchers independently reviewed, extracted and assessed for risk of bias using Covidence software.

Figure 1. PRISMA flow diagram



Results

Table 1. Data were extracted from the studies included for qualitative synthesis (part of extraction is shown below).

Author	Study Design	Intervention	Population	Outcome of Interest	Measurement	Results	Primary Conclusion
Aaron S. Fink MD, et al.	RCT	iMedConsent program	Veterans who were scheduled for 1 of the 4 surgeries: carotid endarterectomy (CEA), laparoscopic cholecystectomy, radical prostatectomy, and total hip arthroplasty	5 primary outcome measures: patient comprehension of surgery, patient satisfaction with decision-making, patient satisfaction with health care, patient anxiety about surgical procedure, and provider use of and satisfaction with iMedCon-sent (no RB and RB)	Rapid Estimate of Adult Literacy and customized questionnaires developed	There was a statistically significant difference in total mean comprehension scores for all operations between the RB group (71.4% correct) and the no RB group (68.2%correct), P0.03. The effect was greatest in the CEA group, 73.4% for RB versus 67.7% for no RB (P0.02). Other surgical types all had higher comprehension in the RB group, but the differences were not statistically significant	Addition of RB to a standardized computer-based consent program significantly improved patient comprehension; the effect was greatest in patients undergoing CEA and for understanding overall and key risks of the surgical procedure.
Jennifer K. Carroll	RCT	Six 90-min group training sessions for ePersonal Health Record using cell phone and one 20–30 min individual pre-visit coaching session	Patients with confirmed HIV diagnosis, age≥18 years, and receipt of HIV/primary care at a participating clinic site.	Patient activation	Patient Activation Measure (PAM). Secondary outcomes: changes in eHealth literacy, Decision Self-efficacy, Perceived Involvement in Care Scale, health (SF-12), receipt of HIV-related care, and change in HIV viral load	Intervention significant difference compared to control group, the PAM (difference 2.82: 95% confidence interval [CI] 0.32–5.32). Effects were largest among participants with lowest quartile PAM at baseline (p< 0.05). The intervention doubled the odds of improving one level on the PAM (odds ratio 1.96; 95% CI 1.16–3.31).	Patient activation and empowerment were improved through use of intervention

Table 2. Summary of studies included in systematic review.

Intervention Category	Studies Utilized (n)	Example
Verbal / Written Tools	7	Brochures, simplified ICF, verbal feedback with clinicians
Multimedia / Technology based interventions	7	Entertainment-decision aids, computerized interactive tools, videos, and pictograms
Combination	8	Mobile devices along with verbal training

Discussion & Conclusion

- Addressing health literacy in clinical trials resulted in improved comprehension, retention, decision-making, knowledge, and satisfaction. Incorporating health literacy principles into clinical trials may lead to trial success and patient activation.
- It is especially important to address health literacy in trials among minority populations, and future research must focus on identifying most appropriate literacy tools for diverse populations.
- Additional efforts need to be implemented to improve health literacy in all types of patient research communications, beyond informed consent. A follow-up systematic review of this "gray" literature is recommended to further examine relevant and updated measures of health literacy in clinical trials.

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