# The Use of Web Techniques for Reviewing RCT PILs

## Using Content Analysis of Text and Amazon Crowdsourcing to Acquire, Measure, and Analyse Public Feedback on Patient Information Leaflets for Clinical Trials.

# Research Abstract

## Background and Aim

Clinical trials have become the corner stone (Lovato, Hill, Hertert, Hunninghake, & Probstfield, 1997) for identifying high-quality interventions in the health-care systems of developed countries. They enable researchers to compare the effects of new drugs and treatments against those that are currently employed, to improve the health of the general population by developing new guidelines and practices (NHS, 2017). On the other hand, their very nature implies a risk for the patients who choose to participate, of either receiving a sub-optimal treatment or suffering previously undiscovered side-effects (Moore & Savage, 2002). Thus, it is of great importance to ensure that the patient is aware of these risks and to enforce good ethical practice during recruitment (MRC, 2016).

One of the core tasks for any UK clinical trial is therefore to develop a Patient Information Leaflet (PIL) that is able to inform patients about essential trial features. The current process for clinical research is based on the NHS proportionate approach to consent (HRA, 2017), which enables most PILs for Randomised Controlled Trials (RCTs) to be designed by filling in a template form provided by the HRA which is then reviewed by an Ethics Panel as part of the research submission process. Nonetheless, even though such PILs are required by the HRA as an essential part of any RCT (NHS, 2017), several recent studies have found that most PILs have serious issues that undermine their capacity to inform patients, despite fulfilling the legal requirements and following NHS recommended guidelines and templates (Reinert, et al., 2014) (Gillies, Huang, Skea, Brehaut, & Cotton, 2014) (Poplas-Susíc, Klemenc-Ketis, Kersnik, & others, 2014) (Knapp, Raynor, Silcock, & Parkinson, 2011) (Nicholls, Hankins, Hooley, & Smith, 2009).

Several different approaches have sought to address these issues, from employing quantitative content analysis of the PILs text to alternative methods for engaging with Patient and Public Involvement (PPI) groups. However, improving the quality of PILs remains a research priority, as evidenced by The Health Research Board Trials Methodology and Networks (TMRN) work with the James Lind Alliance and the TrialBank setting priorities for trial recruitment research (Healy, et al., 2018). Specifically, identifying which information should be communicated to patients, assessing the effect of PPI collaboration on recruitment rates and finding the best methods to deliver information are among the top five questions identified by this JLA priority-setting panel (Healy, et al., 2018). Therefore, the aim of this project is to build a tool that supports the quantitative assessment of PIL readability and the ease of understanding of essential trial features, and to compare the effects of several techniques on this.

The first phase of our study was exploration of the textual characteristics of trial PILs and the type of comments expected from revisions from a PPI group. Based on this information, we constructed a Web platform to collect public comments online, link these comments to specific sections of the PIL, assess the health literacy skill of public revisers of PILs, and quantitatively identify sentences which require a higher literacy level than the public normally have. The final study employs Amazon crowdsourcing (with and without extra support) to obtain rewritten versions of these sentences, and determines whether they are indeed easier to understand.

The overall contribution of this research is to understand the challenges posed by current PILs for recruiting participants to RCTs and the value of using members of the public recruited online to improving PIL readability. This should yield a fast, cost effective alternative to current processes for reviewing and improving PILs, and thus better informed trial participants.

# References

Association, W. A. (2007). Web Analytics Definitions. Retrieved from https://www.digitalanalyticsassociation.org/Files/PDF\_standards/WebAnalyticsDefinitionsVol1.pdf

Escudero-Carretero, M. J., S{\'a}nchez-G{\'o}mez, S., Gonz{\'a}lez-P{\'e}rez, R., Sanz-Amores, R., Prieto-Rodr{\'\i}guez, M. A., & Fern{\'a}ndez de la Mota, E. (2013). Elaboración y validación de un documento informativo sobre adeno-amigdalectomı́a para pacientes. *Anales del sistema sanitario de Navarra*, *36*, pp. 21-33.

Gillies, K., Huang, W., Skea, Z., Brehaut, J., & Cotton, S. (2014). Patient information leaflets (PILs) for UK randomised controlled trials: a feasibility study exploring whether they contain information to support decision making about trial participation. *Trials, 15*, 62.

Grimes, S. (2007). A brief history of text analytics. *BeyeNetwork, October, 30*, 2007.

Healy, P., Galvin, S., Williamson, P. R., Treweek, S., Whiting, C., Maeso, B., . . . others. (2018). Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership--the PRioRiTy (Prioritising Recruitment in Randomised Trials) study. *Trials, 19*, 147.

HRA. (2017, January 17). Appliying a proportionate approach to the process of seeking consent - HRA Guidance.

Knapp, P., Raynor, D. K., Silcock, J., & Parkinson, B. (2011). Can user testing of a clinical trial patient information sheet make it fit-for-purpose?-a randomized controlled trial. *BMC medicine, 9*, 89.

Lovato, L. C., Hill, K., Hertert, S., Hunninghake, D. B., & Probstfield, J. L. (1997). Recruitment for controlled clinical trials: literature summary and annotated bibliography. *Controlled clinical trials, 18*, 328-352.

MHRA. (2016). Best Practice Guidance on Patient Information Leaflets. MHRA. Retrieved from https://www.gov.uk/government/publications/best-practice-guidance-on-patient-information-leaflets

Moore, L., & Savage, J. (2002). Participant observation, informed consent and ethical approval. *Nurse Researcher, 9*, 58-69.

Moult, B., Franck, L. S., & Brady, H. (2004). Ensuring quality information for patients: development and preliminary validation of a new instrument to improve the quality of written health care information. *Health Expectations, 7*, 165-175.

MRC. (2016). Consent and Participant Information Sheet Preparation Guidance. NHS. Retrieved from http://www.hra-decisiontools.org.uk/consent/principles-general.html

NHS. (2017). Clinical trials. Retrieved from http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Nicholls, S., Hankins, M., Hooley, C., & Smith, H. (2009). A survey of the quality and accuracy of information leaflets about skin cancer and sun-protective behaviour available from UK general practices and community pharmacies. *Journal of the European Academy of Dermatology and Venereology, 23*, 566-569.

Poplas-Susíc, T., Klemenc-Ketis, Z., Kersnik, J., & others. (2014). Usefulness of the patient information leaflet (PIL) and information on medicines from professionals: a patients' view. A qualitative study. *Zdravni{\v{s}}ki Vestnik, 83*, 368-375.

Reinert, C., Kremmler, L., Burock, S., Bogdahn, U., Wick, W., Gleiter, C. H., . . . Hau, P. (2014). Quantitative and qualitative analysis of study-related patient information sheets in randomised neuro-oncology phase III-trials. *European Journal of Cancer, 50*, 150-158.