“Informed” or Informed Consent: Is Digital Better, and for Whom?

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Recently, one of the authors’ fathers underwent surgery. At the pre-operative briefing, the anaesthetist noticed there was no signed informed consent (SIC). The doctors asked for the father’s consent as he was wheeled into the operating theatre, in no state to read or sign any document. And yet sign he did. While SIC is “…a pragmatic step that can be easily handled and even enforced”[[1]](#footnote-1), one question is how to obtain it?

In our time-constrained practices, delegating the task of obtaining SIC to a digital platform could save precious time and effort, allowing patients to engage with the SIC at their own pace. Indeed, a meta-analysis has reported that SIC interventions have increased patients’ satisfaction with the decision-making process, alongside providing lasting knowledge, while not provoking anxiety[[2]](#footnote-2). Likewise, in a systematic review, most research and clinical digital SIC (DSIC) tools had at least one positive outcome[[3]](#footnote-3): Embedding interactivity in DSIC also improved comprehension.[[4]](#footnote-4)

DSIC also improves emotional measures: Patients report higher satisfaction, perceived ease of use, and increased ability to complete the consent form independently. [[5]](#footnote-5), This could possibly reduce or prevent cases like that of the father.

But would DSIC help all patients?

The answer is – maybe. Physicians and patients have questioned whether SIC for long term opioid therapy was really informed, suggesting that comprehension of SIC needed to be improved[[6]](#footnote-6). Similarly, a study of cancer patients and opioid education indicated a need for plain language explanations, and culturally appropriate communication.[[7]](#footnote-7) These findings align with the realization that patients from low income backgrounds tend to have low health and digital literacy, which limit both their access to digital healthcare and its effectiveness once utilized[[8]](#footnote-8).

Having low-literacy individuals use DSIC warrants the use of simplified language and the possibility to augment the SIC tool with an audio-visual digital encounter, such that it will allow rural populations to sign up for clinical trials[[9]](#footnote-9).

DSIC holds much promise. Yet, we must identify who feels redlined from DSIC, and find ways to engage them – digitally or otherwise - thereby achieving truly informed consent.

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החתימה תיערך מול עו"ד ליאור קיל במשרד שוב-גל לא תהיה.

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1. Miron-Shatz T. Your Life Depends on It: What You Can Do to Make Better Choices about Your Health.Basic Books, 2021. P. 16. [↑](#footnote-ref-1)
2. Kinnersley P, et al. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. *Cochrane Database of Systematic Reviews* 2013; 7. [↑](#footnote-ref-2)
3. Gesualdo F, et al. Digital tools in the informed consent process: a systematic review. *BMC medical ethics* 2021; 22.1: 1-10. [↑](#footnote-ref-3)
4. Geier C, Adams RB, Mitchell KM, & Holtz BE. Informed Consent for Online Research—Is Anybody Reading?: Assessing Comprehension and Individual Differences in Readings of Digital Consent Forms. *Journal of Empirical Research on Human Research Ethics* 2021; *16*(3), 154-164. [↑](#footnote-ref-4)
5. Abujarad F, et al. Comparing a Multimedia Digital Informed Consent Tool With Traditional Paper-Based Methods: Randomized Controlled Trial. *JMIR formative research* 5.10 2021; e20458. [↑](#footnote-ref-5)
6. # Signature Informed Consent for Long-Term Opioid Therapy in Patients With Cancer: Perspectives of Patients and Providers

Author links open overlay panel[Karleen F.GiannitrapaniPhD, MPHaSorayaFereydoonibAzinAzarfarMDcMaria J.SilveiraMD, MPHdPeter A.GlassmanMBBS, MSceAmanda M.MidboePhDfAmy B.S.BohnertPhD, MHSgMaria A.ZenoniMShRobert D.KernsPhDiRobert A.PearlmanMD, MPHjSteven M.AschMD, MPHaWilliam C.BeckerMDkKarl A.LorenzMD, MSHSa](https://www.sciencedirect.com/science/article/abs/pii/S0885392419305068#!) [↑](#footnote-ref-6)
7. Our findings highlight the need for effective cancer education and communication about opioid agonist treatment and POM in plain simple language that is easy to understand, relevant, and culturally appropriate. Recommendations for cancer education and suggestions for future research are discussed.

Tyson DM, et al. Understanding cancer survivors’ educational needs about prescription opioid medications: implications for cancer education and health literacy. *Journal of Cancer Education* 2021; 36.2: 215-224. [↑](#footnote-ref-7)
8. Viswanathan M, et al. A bottom-up approach to understanding low-income patients: Implications for health-related policy. *Journal of Law, Medicine & Ethics* 2018; 46.3: 658-664. [↑](#footnote-ref-8)
9. Clark D, et al. Digital informed consent in a rural and low-income population. *JAMA cardiology* 2020; 5.7: 845-847. [↑](#footnote-ref-9)