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governance, ethics, evidence, policy, practice

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

September 2023 :: Issue 57

This digest aggregates and distills key content addressing informed consent from a broad spectrum of peer-reviewed journals and grey literature, and from various practice domains and organization types including international agencies, INGOs, governments, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations.

In preparing this digest, we monitor a broad range of academic journals and utilize *Google Scholar* [search terms "consent", "informed consent", and "assent" in title and available text]. After careful consideration, a selection of these results appear in the digest. We also monitor other research, analysis, guidance and commentary beyond the academic journal literature globally, including calls for public consultation and symposia/conferences which address consent/assent in whole or in part. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

Informed Consent: A Monthly Review is a service of the Center for Informed Consent Integrity (CICI), a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

Editor
Paige Fitzsimmons, MA
Associate Director, Center for Informed Consent Integrity
Associate Fellow
GE2P2 Global Foundation
paige.fitzsimmons@ge2p2global.org

We organize content in this digest using subject categories to help readers navigate to areas of interest. We expect that these categories will evolve over time. We lead each edition with a spotlight section highlighting articles which the editorial team has assessed to be strategically important and well aligned to our thematic focus areas of governance, ethics, policy and practice. The full citation/abstract for each spotlight item appears just below the summary beginning that section. Active subject areas in this edition include:

RIGHTS/LEGAL/LEGISLATIVE	13
MEDICAL/SURGICAL	15
GENERAL/OTHER	19

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
FREE PRIOR INFORMED CONSENT (FPIC)
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
POLICY/GUIDANCE/CODES/PROGRAM ACTION

Please note that while we strive to identify the primary subject area for the categorization of the monthly digest we also recognize that many articles are relevant across other subject areas. We encourage readers to review the entire digest and to utilize the search function on our website where articles are cross tagged. We maintain a glossary, an inventory of assessment and other tools, as well as standards and guidance documents, also on the website.

UPCOMING CALLS FOR PUBLIC CONSULTATION

We will selectively include calls for public consultation from multilateral agencies, governments, INGOs and other sources where there is a clear intersection with consent/assent. This might be obvious from the title of the draft guidance, regulations, etc., but more often, it will be a thematic area or topic – if properly addressed at all. If you would like to explore participation with our working group developing submissions for these calls, please contact us [david.r.curry@ge2p2global.org].

Public Consultation: ICH E6(R3) [GCP] Principles, Annex 1 and Annex 2

ICH - The E6(R3) EWG is working on the revision of the E6(R2) Guideline "Good Clinical Practice" (GCP) with a view to addressing the application of GCP principles to the increasingly diverse trial types and data sources being employed to support regulatory and healthcare related decision-making on drugs, and provide flexibility whenever appropriate to facilitate the use of technological innovations in clinical trials.

Public consultation dates:

ANVISA, Brazil - Deadline for comments by 31 August 2023
EC, Europe - Deadline for comments by 26 September 2023
FDA, United States - Deadline for comments by 5 September 2023
HSA, Singapore - Deadline for comments by 30 September 2023
Health Canada, Canada - Deadline for comments by 20 October 2023
MHLW/PMDA, Japan - Deadline for comments by 9 September 2023
MHRA, UK - Deadline for comments by 31 August 2023
NMPA, China - Deadline for comments by 31 August 2023
Swissmedic, Switzerland - Deadline for comments by 26 September 2023
TFDA, Chinese Taipei - Deadline for comments by 31 August 2023

Public consultation on WHO guidance for best practices for clinical trials

WHO -19 July 2023

Call for consultation: Deadline 15 Sep 2023

WHO launches a global stakeholder survey on solutions for strengthening clinical trial infrastructure and capacity.

This global stakeholder survey will be open until 10th September 2023.

The outcomes of the public consultation and the global survey will guide the WHO in a series of upcoming regional and global consultations with Member States and non-State-actors towards the implementation of the WHA resolution 75.8 on clinical trials.

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SYMPOSIA/CONFERENCES

We will selectively include information on major symposia and conferences which address issues, evidence, analysis or debates involving consent/assent. This listing will include [1] meetings already concluded but which are posting presentations/recordings, etc.; [2] future meeting which have posted registration/logistics information, and [3] meetings which have announced calls for abstracts/panels, etc.

17th World Congress of Bioethics

3-6 June 2024
Doha, Qatar

The WCB 2024 theme is "Religion, Culture, and Global Bioethics". This theme aims to engage bioethics researchers from a broad range of fields and disciplines and to take full advantage of hosting the WCB in the Arab-Muslim world and the Middle East

Call for Abstracts now open, deadline September 30, 2023.

> ***Editor's Note:*** *We are certainly aware of the continuing, active debate in the bioethics community and beyond about the site selection for this meeting. The Foundation is reviewing its options regarding participation, submitting abstracts, etc.*

8th World Conference on Research Integrity (Hybrid)

2-5 June 2024
Megaron Athens International Conference Centre (MAICC)
Athens, Greece

The biannual WCRIs cater to all disciplinary fields, all professional ranks, and all career stages, and involve all stakeholders in research integrity, including universities, research institutes, research funders, publishers, and governments. Each WCRI emphasises a specific theme, but all cater for the whole range of research integrity issues and responsible research practices. The 8th WCRI will put thematic emphasis on: *Catalysing the translation of research into trustworthy policy and innovation.*

Call for Abstracts now open, deadline October 17, 2023.

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SPOTLIGHT ARTICLES

In this issue's *Spotlight* section we include two recent articles analyzing the structure and components of ICFs [informed consent forms].

In **Characterization of Key Information Sections in Informed Consent Forms Posted on ClinicalTrials.gov** published in *the Journal of Clinical Translational Science* the authors assess the presence, length, readability

and other parameters of KIs [key information sections] in ICFs posted on ClinicalTrials.gov in alignment with the revised Common Rule. The authors argue that "…widely adopted guidelines could also facilitate compliance analyses that are currently challenged by the broad subjectivity in interpreting the KI requirement [in the revised Common Rule]."

In the *Perspectives in Clinical Research* article **Redefining informed consent form in cell and gene therapy trials***,* Dalal et at. address the need to adapt the informed consent process and ICFs to the unique context of gene therapy trials [see Fig 3 below] as well as the cultural contexts in which the trials are implemented.

Characterization of Key Information Sections in Informed Consent Forms Posted on ClinicalTrials.gov

Luke Gelinas, Walker Morrell, Tony Tse, Ava Glazier, Deborah A. Zarin, Barbara E. Bierer

Journal of Clinical and Translational Science, 14 August 2023

Abstract

Introduction

Recent revisions to the United States Federal Common Rule governing human studies funded or conducted by the federal government require the provision of a "concise and focused" key information (KI) section in informed consent forms (ICFs). We performed a systematic study to characterize KI sections of ICFs for federally-funded trials available on ClinicalTrials.gov.

Methods

We downloaded ICFs posted on ClinicalTrials.gov for treatment trials initiated on or after the revised Common Rule effective date. Trial records (n=102) were assessed by intervention type, study phase, recruitment status, and enrollment size. The ICFs and their KI sections, if present, were characterized by page length, word count, readability, topic, and formatting elements.

Results

Of the 102 trial records, 76 had identifiable KI sections that were, on average, 10% of the total length of full ICF documents. KI readability grade level was not notably different than other sections of ICFs. Most KI sections were distinguished by section headers and included lists but contained few other formatting elements. Most KI sections included a subset of topics consistent with the basic elements of informed consent specified in the Common Rule.

Conclusion

Many of the KI sections in the study sample aligned with practices suggested in the preamble to the revised Common Rule. Further, our results suggest that some KI sections were tailored in study-specific ways. Nevertheless, guidelines on how to write concise and comprehensible KI sections would improve the utility and readability of KI sections.

Redefining informed consent form in cell and gene therapy trials

Review Article

Varsha Dalal, Geeta Jotwani, Munna Lal Yadav

Perspectives in Clinical Research, 28 July 2023

Abstract

Informed consent is a foundation of the ethical conduct of research involving human participants. Based on the ethical principle of respect for persons, the goal of informed consent is to ensure that participants are aware of the risks and potential benefits and make a voluntary decision about participating in clinical trial research. The extraordinary scientific advances happening globally have demonstrated the potential of regenerative therapies in transforming the health of the nation by providing a therapeutic option for diseases that were previously considered incurable. These therapies, which include cells and gene therapy (GT) labeled as Advanced Therapeutic Medicinal Products globally, have complex mechanisms of action. Owing to their highly personalized and intricate nature of these therapies, developing the latter often presents unique challenges above and beyond those encountered for small molecule drugs. We recently looked through some cell and GT clinical trials and realized the lacunae in the informed consent form (ICF) provided by the

investigators. Especially in a country like India, where the general understanding and perception of patients is limited regarding clinical trials, it is felt that any lapses in the consent process may jeopardize the informed decision-making and safety of the participants and tarnish the reputation of India globally. The present article highlights the need for appropriate patient and public education on the various aspects of cell and gene therapies and aims to address all the elements of ICF in light of the challenges associated with these innovative therapies.

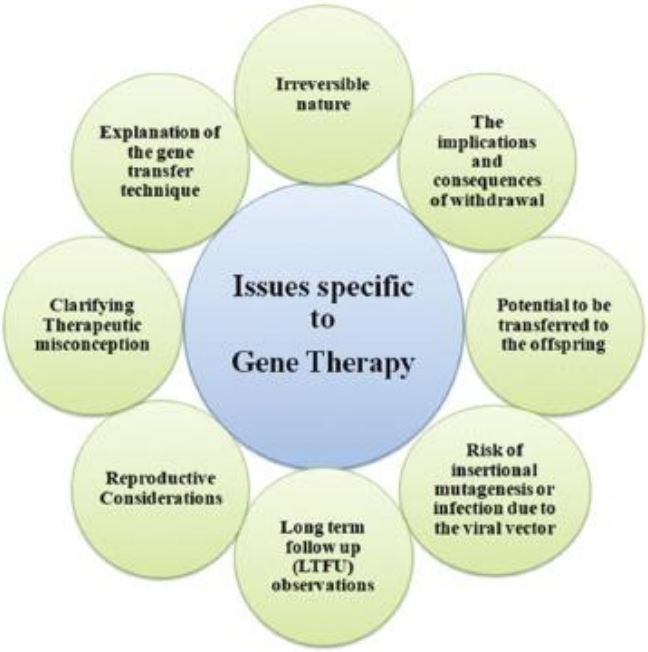

Figure 3: Different important issues related to Gene therapy trials

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BIOMEDICAL RESEARCH

Consent document translation expense hinders inclusive clinical trial enrolment

Maria A. Velez, Beth A. Glenn, Maria Garcia-Jimenez, Amy L. Cummings, Aaron Lisberg, Andrea Nañez, Yazeed Radwan, Jackson P. Lind-Lebuffe, Paige M. Brodrick, Debory Y. Li, Maria J. Fernandez-Turizo, Arjan Gower, Maggie Lindenbaum, Manavi Hegde, Jenny Brook, Tristan Grogan, David Elashoff, Michael A. Teitell, Edward B. Garon

Nature, 2 August 2023

Abstract

Patients from historically under-represented racial and ethnic groups are enrolled in cancer clinical trials at disproportionately low rates in the USA. As these patients often have limited English proficiency, we hypothesized that one barrier to their inclusion is the cost to investigators of translating consent documents. To test this hypothesis, we evaluated more than 12,000 consent events at a large cancer centre and assessed whether patients requiring translated consent documents would sign consent documents less frequently in studies lacking industry sponsorship (for which the principal investigator pays the translation costs) than for industry-sponsored studies (for which the translation costs are covered by the sponsor). Here we show that the proportion of consent events for patients with limited English proficiency in studies not sponsored by industry was approximately half of that seen in industry-sponsored studies. We also show that among those signing consent documents, the proportion of consent documents translated into the patient's primary

language in studies without industry sponsorship was approximately half of that seen in industry-sponsored studies. The results suggest that the cost of consent document translation in trials not sponsored by industry could be a potentially modifiable barrier to the inclusion of patients with limited English proficiency.

Advance Consent In Acute Stroke Trials: Survey Of Canadian Research Ethics Board Chairs

Manuscript

Rena Seeger, Ubong Udoh, Brian Dewar, Stuart Nicholls, Mark Fedyk, Robert Fahed, Jeff Perry, Michael D Hill, Bijoy Menon, Richard H Swartz, Alexandre Y Poppe, Sophia Gocan, Jamie Brehaut, Katie Dainty, Victoria Shepherd, Dar Dowlatshahi, Michel Shamy

24 July 2023 [Cambridge University Press]

Abstract

Advance consent could allow individuals at high risk of stroke to provide consent before they might become eligible for enrollment in acute stroke trials. This survey explores the acceptability of this novel technique to Canadian Research Ethics Board (REB) chairs that review acute stroke trials. Responses from 15 REB chairs showed that majority of respondents expressed comfort approving studies that adopt advance consent. There was no clear preference for advance consent over deferral of consent, although respondents expressed significant concern with broad rather than trial-specific advance consent. These findings shed light on the acceptability of advance consent to Canadian ethics regulators.

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SOCIAL SCIENCE RESEARCH

Continuous quality improvement: reducing informed consent form signing errors

Research

Tsui-Wen Hsu, Chi-Hung Huang, Li-Ju Chuang, Hui-Chen Lee, Chih-Shung Wong

BMC Medical Ethics, 4 August 2023; 24(59)

Open Access

Abstract

Background

Adherence to ethical guidelines and regulations and protecting and respecting the dignity and autonomy of participants by obtaining a valid informed consent form (ICF) prior to participation in research are crucial; The subjects did not add signatures next to the corrections made to signatures or dates on the ICF, Multiple signatures in other fields, ICF missing/missing signature, Incorrect ICF version Signed after modification, Correction tape used to correct signature, Impersonated signature, Non-research-member signature, however, ICFs are often not properly completed, which must be addressed. This study analyzed ICF signing errors and implemented measures to reduce or prevent these errors.

Methods

We used the plan–do–check–act (PDCA) cycle to help improve the correctness and validity of ICF signing.

Results

Interim and final reports from January 2016 to February 2020 including 363 ICFs were studied. The total proportion of correct ICF signatures (200, 83.3%) following the PDCA intervention was significantly higher than that before the intervention ($P < 0.05$). Analysis of the types of signing error demonstrated that signature errors were significantly reduced after the intervention, particularly for subjects did not add signatures next to the corrections made to signatures or dates on the ICF (16, 6.7%) and impersonated signature (0; $P < 0.05$).

Conclusions

The proportions of other error types—multiple signatures in other fields, missing or unsigned ICF, incorrect signature order, incorrect ICF version, use of correction tape to correct signature, and non-medical profession members signing the ICF—did not differ significantly.

Physician-Investigator, Research Coordinator, and Patient Perspectives on Dual-Role Consent in Oncology A Qualitative Study

Stephanie R. Morain, Dorit Barlevy, Steven Joffe, Emily A. Largent

JAMA Network Open, 25 July 2023; 6(7)

Abstract

Importance

Classic statements of research ethics generally advise against dual-role consent in which physician-investigators seek consent for research participation from patients with whom they have preexisting treatment relationships. Yet dual-role consent is common in clinical oncology research, as studies are often conducted in close relationship with clinical care.

Objective

To explore key stakeholders' perspectives on dual-role consent in clinical oncology trials.

Design, Setting, and Participants

This qualitative study with 43 participants was conducted at a National Cancer Institute–designated comprehensive cancer center from 2018 to 2022. Semistructured qualitative interviews of physician-investigators, research coordinators, and patients were performed. Respondents were recruited from 3 populations: (1) physician-investigators engaged in clinical oncology research; (2) research coordinators engaged in clinical oncology research; and (3) patients, with and without prior clinical trial experience, who had received a new cancer diagnosis at least 2 months prior to enrollment in this study.

Main Outcomes and Measures

Interviews were audio recorded and professionally transcribed. A thematic analysis approach was used to develop a codebook that included both theory-driven, a priori codes and emergent, inductive codes. Two authors double-coded all transcripts and met regularly to compare coding, discuss discrepancies, refine the codebook, and draft memos describing relevant themes and their frequency.

Results

Among the 43 respondents, 28 (65.1%) were female; 9 (20.9%) were African American, 8 (18.6%) were Asian, 6 (14.0%) were Hispanic, and 21 (48.8%) were White; 15 were physician-investigators (6 [40.0%] with 6-10 years of experience, 4 [26.7%] with at least 20 years of experience), 13 were research coordinators (5 [38.5%] with 0-5 years of experience, 5 [38.5%] with 6-10 years of experience), and 15 were patients (9 [60.0%] aged 46-64 years). Four main themes were found: interviewees (1) perceived greater potential for role synergy than for role conflict; (2) reported dual-role consent as having mixed effects on the consent process, increasing prospective participants' understanding and likelihood of agreement while also challenging voluntariness; (3) preferred a team-based approach to the consent process in which physician-investigators and research coordinators share responsibility for communicating with prospective participants and safeguarding voluntariness; and (4) offered strategies for managing tensions in dual-role consent.

Conclusions and Relevance

This qualitative study found that concerns about dual-role consent in clinical oncology, while valid, may be outweighed by corresponding advantages, particularly if appropriate mitigation strategies are in place. These findings support a team-based approach to informed consent, in which physician-investigators and research coordinators promote both the understanding and voluntariness of prospective participants.

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HEALTH DATA/DATA

Dynamic consent, communication and return of results in large-scale health data reuse: Survey of public preferences

Sam Ha Muller, Ghislaine Jmw van Thiel, Menno Mostert, Johannes Jm van Delden

Digit Health, 16 August 2023

Open Access

Abstract

Dynamic consent forms a comprehensive, tailored approach for interacting with research participants. We conducted a survey study to inquire how research participants evaluate the elements of consent, information provision, communication and return of results within dynamic consent in a hypothetical health data reuse scenario. We distributed a digital questionnaire among a purposive sample of patient panel members. Data were analysed using descriptive and nonparametric inferential statistics. Respondents favoured the potential to manage changing consent preferences over time. There was much agreement between people favouring closer and more specific control over data reuse approval and those in favour of broader approval, facilitated by an opt-out system or an independent data reuse committee. People want to receive more information about reuse, outcomes and return of results. Respondents supported an interactive model of research participation, welcoming regular, diverse and interactive forms of communication, like a digital communication platform. Approval for reuse and providing meaningful information, including meaningful return of results, are intricately related to facilitating better communication. Respondents favoured return of actionable research results. These findings emphasize the potential of dynamic consent for enabling participants to maintain control over how their data are being used for which purposes by whom. Allowing different options to shape a dynamic consent interface in health data reuse in a personalized manner is pivotal to accommodate plurality in a flexible though robust manner. Interaction via dynamic consent enables participants to tailor the elements of participation they deem relevant to their own preferences, engaging diverse perspectives, interests and preferences.

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CAPACITY TO CONSENT

Treatment without consent in adult psychiatry inpatient units: a retrospective study on predictive factors

Giulia Meroni, Othman Sentissi, Stefan Kaiser, Alexandre Wullschleger

Frontiers of Psychiatry, 10 August 2023

Abstract

Background

Coercion is one of the most important challenges in mental health. In Switzerland, forced medication can be applied during an emergency (Art. 435 of the Civil Code) or over a longer period in case of endangerment of others or oneself (Art. 434). We aimed to analyze the predictors of this specific treatment without consent.

Methods

Forced medication prescriptions in the Division of Adult Psychiatry of the Geneva University Hospitals between 2018 and 2021 were retrospectively analyzed. Medication under Article 434 was the main outcome variable. Age, gender, admission mode, main diagnosis, and the Health of the Nation Outcome Scales (HoNOS) score at admission were considered as potential predictors. T-test and Pearson's chi-square test were used to compare continuous and categorical variables. A logistic regression was performed to find significant predictors of forced medication.

Results

Seventy-one out of 4,326 inpatients were subjected to forced medication under Art. 434. HoNOS global scores at admission were not significantly different in the forced medication group compared to the control group. Aggressive behavior was lower in the former at the univariate level. Forced medication was associated at the multivariate level with female gender, involuntary admission, and psychosis.
Conclusion
Women suffering from psychosis are more at risk of receiving involuntary and repeated medication. The risk of deterioration in psychosocial functioning or behavioral disorganization seems to be the main argument for this coercive measure. Future studies should focus on the patient's perception of this coercion to prevent it and improve adherence to care. Follow-up after discharge might be useful to evaluate a long-term benefit.

Ensuring Ethical Dental Care: Obtaining Legal Consent for Nonverbal Adults

TDIC Risk Management Staff
Journal of the California Dental Association, 28 July 2023
Excerpt
When it comes to dental treatment, the importance of obtaining proper, legal consent cannot be overstated. Dentists often face unique challenges in obtaining consent to treat adults who are nonverbal or unable to provide consent on their own due to cognitive impairments or advanced age.
The Dentists Insurance Company Risk Management Advice Line, which provides guidance to TDIC policyholders and dental association members, regularly receives inquiries about the appropriate procedures for obtaining consent to treat adults with special needs. The following case study illustrates the need for compassionate care and vigilance to ensure valid consent is obtained…

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YOUNG PERSONS

Adolescent Consent

Book Chapter
Y. Tony Yang, Dorit R. Reiss
Vaccine Law and Policy, 25 August 2023 [Springer]
Abstract
State law generally controls whether parental consent is required for minors who may want to make their own health care decisions—including vaccination (English et al., J Adolesc Health 53:550–551, 2013.). This means that in many states, teenagers under the age of 18 cannot decide for themselves about whether or not to get vaccinated against diseases like diphtheria, measles, polio, or COVID. Lower vaccination rates put unvaccinated individuals and others in their communities at risk (Weithorn and Reiss, Conn Law Rev 52:771, 2020.). One proposal to address this issue is to create a limited exception to parental decision-making authority by permitting certain older minors to legally consent to approved vaccinations, and protecting the confidentiality of minors who request vaccination without parental consent. The law allows similar exceptions for minors to make healthcare and treatment decisions independent of parental consent in other contexts. This chapter explores the issues related to adolescent consent to vaccination. We provide a brief overview of the legal landscape of health care decision authority for minors. We then discuss related issues and considerations. Next, we suggest a legislative solution for adolescent consent. Finally, we conclude that minors and the state have compelling interests for reform to vaccination consent laws.

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TECHNOLOGY/OTHER MEDIATION

Improving the Consent Process with an Informed Consent Video Prior to Outpatient Colonoscopy

Original Research

Emily W. Lopes, Leo Boneschansker, Jacqueline N. Chu, James M. Richter, Amiko M. Uchida, Paul Lochhead

Gastro Hep Advances, 28 July 2023

Abstract

Background & Goals

Informed consent should allow patients appropriate time and conditions to make decisions about their care. However, consent is often obtained immediately prior to colonoscopy. We conducted a quality improvement study to assess how a pre-procedure consent video two days prior to outpatient colonoscopy impacts patient satisfaction.

Study

Patients undergoing outpatient colonoscopy at a large academic medical center opted-in to a text-messaging platform for procedural information. Our intervention was an informed consent video two days before colonoscopy. Our primary outcome was a composite patient satisfaction score. Pre- and post-intervention scores were compared using ordinal or multinomial logistic models to calculate odds ratios (OR) or relative risk ratios (RRR) and 95% confidence intervals (CI), adjusting for age and sex.

Results

1,109 and 1,452 patients completed ≥1 survey question in the pre- and post-intervention phases, respectively. Overall patient satisfaction did not differ between groups [OR for a 1-point increment in satisfaction score between post- vs. pre-intervention groups=1.05; 95% CI: 0.90-1.22; p=0.51]. Compared to pre-intervention, post-intervention respondents were more likely to report higher satisfaction with time available to talk with their physician (OR of a 1-point increase in individual question response=1.29; 95% CI: 1.09-1.54; p=0.004). Compared to pre-intervention, more physicians in the post-intervention phase rated satisfaction with consent process efficiency as “very satisfied” or “satisfied” (p<0.001).

Conclusion

An informed consent video prior to colonoscopy resulted in similar overall patient satisfaction. However, post-intervention, patients were more likely to report sufficient time to talk with their physician, and physicians reported higher satisfaction with consent efficiency.

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CULTURAL/COUNTRY CONTEXT

Surgical Informed Consent in Clinical Practice: Patients’ Perspective Undergoing Cesarean Section at Three Teaching Hospitals in Addis Ababa, Ethiopia

Eskinder Kebede, Tadios Tasew, Dawit Worku

Ethiopian Journal of Health Sciences, 17 August 2023

Abstract

Background

Informed consent is a communication process of providing the patient/parents/guardians with relevant information regarding the diagnosis and the treatment so that they can make informed decisions. This study was to assess the practice of surgical informed consent in Addis Ababa.

Methods

An institution-based cross-sectional study was undertaken in Addis Ababa in 2021. A total of 312 women who underwent cesarean section were interviewed immediately after their hospital discharge. Thirteen

components of SIC were used based on international recommendations, including the Royal College of Surgeons' standards of informed consent practices for surgical procedures.

Results

Almost all (100 %) of the respondents were asked to provide written consent, and 96.2 % of them signed the consent form. Most women (89.4%) received information about the indication(s). Few (18.6%) respondents were informed about the type of anesthesia to be administered while only 9 %(n= 28) of them were given an opportunity to choose the option of anesthesia. Only 44.9% of the respondents have received at least six of the 13 components of SIC suggested by the investigators. In this, the most secured data was the signature of the patient which is 96 %. The least documented element of SIC was alternative treatment.

Conclusion

A majority of women who underwent both elective and emergency cesarean section did not receive comprehensive information during the Surgical Informed Consent process in the study hospitals. There is a need that patients need to be counseled during antenatal visits, specifically when patients visit near term for antenatal checkups.

Knowledge and perception of surgical informed consent among adult surgical patients in Arba Minch and Jinka General Hospitals, Southern Ethiopia

Tigabu Daniel, Yonas Abera, Menaye Yihune

Ethiopian Medical Journal, 4 August 2023

Open Access

Abstract

Background

The surgical informed consent process and format are not uniform nationally and internationally. The objective of this study was to assess the knowledge and perception of adult patients towards the legal nature of surgical informed consent in Arbaminch and Jinka General Hospitals, South Ethiopia.

Methods

Responses from 423 post-operative adult surgical patients were taken using pretested structured interviewer-administered questionnaires for five months. A hospital-based cross-sectional study of all adult surgical patients who were operated were involved before discharged from December 1 2021-April 30, 2022 in Arbaminch and Jinka general hospitals, Southern Ethiopia. Stratified sampling technique was used. The collected data entered into EPI-data version 3.1 and exported to SPSS (version 25) software for statistical analyses. A significant level was determined at a P-value <0.05 with 95% confidence interval.

Results

A total of 423 adults with a response rate of 100% were included in the study. Of the respondent's consent, only 210 (49.6%) was taken by an operating surgeon, and the majority was taken by a general practitioner, nurse, and midwife. Surprisingly consent taken by the porter was 5(1.2%). Of the respondents, only 188(44.4%) had good knowledge and only 58 (13.7%) had a good perception regarding surgical informed consent. Patients exposed for consent signing previously, had 4.06 times higher knowledge than those unexposed (AOR=4.06, 95% CI :-(1.80, 4.492)). Those patients living in an urban area were well aware of surgical informed consent (AOR=0.246, 95% CI:- (0.212, 1.660)). Level of understanding of surgical informed consent, significantly increased for those informed by an operating surgeon (AOR=4.45, 95% CI:- (1.95, 5.09)).

Conclusion

Majority of our patients had poor knowledge and poor perception regarding the legal nature of surgical informed consent. Living in urban, signing informed consent previously and consent taken by operating surgeon affected level of knowledge positively. The consent had to be taken at least by the operating surgeon.

Experiences of patients and next of kin on informed consent process for emergency surgery in two Urban university teaching hospitals in Uganda: a comparative cross sectional study

Research

Olivia Kituuka, Erisa Mwaka, Ian Munabi, Moses Galukande

BMC Emergency Medicine, 2 August 2023; 23(82)

Open Access

Abstract

Informed consent for emergency surgery is a process in which a patient or their next of kin must make quick decisions required for surgery in a life-threatening situation or surgery that may have life-altering outcomes. The objective of the study was to describe patients and their next of kin experiences and factors influencing the informed consent process in two urban university teaching hospitals in Uganda.

Methods

A cross-sectional survey involving patients who underwent emergency surgery and their next of kin was conducted in two tertiary care hospitals; one public and one private-not-for profit institution. A questionnaire was administered to collect sociodemographic information, type of Surgery that was done, how informed consent was obtained and experiences and expectations from the informed consent process. Univariate and multivariate analyses of the variables was done.

Results

We collected data from 210 patients from a public hospital and 170 from a private-not-for profit hospital. Overall, most patients did not have the risks of the surgery communicated to them (79.7%), were not given alternative options (87.6%) and had no opportunity to ask questions (57.4%). Patients at the private institution had 3.35 times the odds of expecting the consent form to be explained to them than those at the public institution. Patients at the public hospital had 0.12 times the odds of preferring to have consent administered by a nurse than patients at the private institution OR 0.12 (0.05–0.29, $p < 0.001$). Patients in the public institution had 0.18 times the odds of preferring to have consent administered by a doctor than patients in the private institution OR 0.18 (0.08–0.45, $p < 0.001$).

Conclusion

Patients in both public and private institutions are not informed about the risks of surgery, alternative options and are not given the opportunity to ask questions. Interpretation of the findings of this study on patient preferences on who administered consent though statistically significant were inconclusive due to the responses not being mutually exclusive.

Consent through art: a critique of a visual method developed with peer-researchers in southern Nepal

Joanna Morrison, Awantika Priyadarshani, Abriti Arjyal

International Journal of Social Research Methodology, August 2023

Abstract

Obtaining informed consent can be challenging during peer research when the boundaries between researcher and participant are blurred. We developed a novel visual consent method with illiterate artists in Nepal who conducted peer interviews in their communities. Artists discussed and sketched images related to ethical principles to create a visual consent form. This improved comprehension about research ethics and developed the confidence of artists to conduct peer interviews, but we found that artists memorised the form; they did not engage participants in looking at the pictures with them; and they did not use the pictures that they disagreed with. In future research, the visuals should be developed in consultation with participants and be used to explain the study to participants. The tool development process can be used to establish a joint understanding about the research, its harms, and benefits, and to develop relational and iterative consent processes in participatory action research.

An examination of the moral conundrum of informed consent within the framework of African values and belief systems : a case study

Jamila Kathoon Adam, Francis Fabian Akpa-Inyang

Interdisciplinary Journal of Economics and Business Law, 2023; 12(1)

Abstract

The notion of bio-medical ethics, which places a strong focus on individual autonomy when considering informed consent, is mostly inspired by western European medical and moral traditions, leaving African traditions and values out of the practice of medical ethics. This is due to the fact that African customs and values favour communitarianism above individualism. In African culture, your strong relationships with people in the community which include sharing everything, including decision-making are what define you as a human being. As a result, it is clear that when applied to the majority of Africans, the idea of individual liberty in informed consent is inapplicable. This is because African communitarian ethics focuses on the interests of the family, community and society and not the individual. Thus, there might be a conflict in the application of the western principle of medical ethics in the general population in Africa. This review paper intends to use published articles, reports, case studies, and ethical principles to explore this potential conflict.

Accessibility of the consent form in Brazilian clinical research

Research

Renan Emilio Kintopp, Sergio Surugi de Siqueira, José Eduardo de Siqueira, José Humberto Guerreiro Tavares Fregnani

Revista Bioética, 2023

Abstract

The informed consent form informs clinical research patients about the nature of the research and their rights, formalizing their decision to participate; however, studies show that this document is written in a complex manner, compromising patient autonomy. Two consent forms from the same hypothetical research were developed with different writing styles and analyzed by the Coh-Metrix Port tool, which evaluates linguistic metrics and textual accessibility. Results showed that both texts were complex and required high schooling level to be understood. These findings reinforce the perception that consent forms may have their real function compromised and point to the importance of changing its elaboration.

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RIGHTS/LEGAL/LEGISLATIVE

Consent for Medical Treatment: What is 'Reasonable'?

Original Article

Abeezar Ismail Sarela

Health Care Analysis, 19 August 2023

Open Access

Abstract

The General Medical Council (GMC) instructs doctors to act 'reasonably' in obtaining consent from patients. However, the GMC does not explain what it means to be reasonable: it is left to doctors to figure out the substance of this instruction. The GMC relies on the Supreme Court's judgment in Montgomery v Lanarkshire Health Board; and it can be assumed that the judges' idea of reasonability is adopted. The aim of this paper is to flesh out this idea of reasonability. This idea is commonly personified as the audience that has to be satisfied by the doctor's justification for offering, or withholding, certain treatments and related information. In case law, this audience shifted from a reasonable doctor to a 'reasonable person in the patient's position';

and Montgomery expands the audience to include 'particular' patients, too. Senior judges have clarified that the reasonable person is a normative ideal, and not a sociological construct; but they do not set out the characteristics of this ideal. John Rawls has conceived the reasonable person-ideal as one that pursues fair terms of co-operation with other members of society. An alternative ideal can be inferred from the feminist ethic of care. However, the reasonable patient from Montgomery does not align with either theoretical ideal; but, instead, is an entirely rational being. Such a conception conflicts with both real-life constraints on rationality and the doctor's duty to care for the patient, and it challenges the practice of medicine.

A Systematic Review Of Patient Perspective On The Informed Consent Doctrine: Ethical And Legal Reflections

Alexander Fiifi Ghartey

UCC Law Journal, July 2023; 3(1) pp 32-56

Abstract

Informed consent is an ethical and legal doctrine of patients' right of acquiescence to treatment and the disclosure of adequate information by the physician to facilitate patients' medical decisions. The doctrine seeks to expand the scope of potential legal liabilities of medical practitioners and to promote patients' rights to medical care. A breach of the informed consent doctrine could be actionable in battery or assault when there is bodily trespass without consent and the tort of clinical negligence when there are inadequate disclosures. This article is a desk-top systematic review of primary data from seven independent empirical studies on informed consent from the perspective of the patient in five common law African countries. The publications which were purposively searched and extracted from Google Scholar reveal that though majority of patients (at least 79 percent) granted consent for treatment, there was insufficient disclosure of material complications or risks, treatment alternatives or the right of patients to refuse medical treatment if they so wished. Disclosures on material risks were as low as 21.2 percent of patients. The physician's competence in providing adequate information disclosure demands continual medical training in the practice of the informed consent doctrine. The application of communication strategies that could enhance patients' capacity to understand the informed consent process is recommended. Additionally, clear guidelines from relevant regulatory bodies are recommended to promote patient rights to informed consent and to protect medical practitioners from potential legal liabilities.

Informed consent for medical student involvement in patient care: an updated consensus statement

Walker S, Reid P, Anderson L, Bull S, Jonas M, Manning J, Merry A, Pitama S, Rennie S, Snelling J, Wilkinson T, Bagg W

The New Zealand Medical Journal, 21 July 2023; 136(1579) pp 86-95

Abstract

Enabling patients to consent to or decline involvement of medical students in their care is an essential aspect of ethically sound, patient-centred, mana-enhancing healthcare. It is required by Aotearoa New Zealand law and Te Kaunihera Rata o Aotearoa Medical Council of New Zealand policy. This requirement was affirmed and explored in a 2015 Consensus Statement jointly authored by the Auckland and Otago Medical Schools. Student reporting through published studies, reflective assignments and anecdotal experiences of students and teachers indicate procedures for obtaining patient consent to student involvement in care remain substandard at times. Between 2020 and 2023 senior leaders of Aotearoa New Zealand's two medical schools, and faculty involved with teaching ethics and professionalism, met to discuss these challenges and reflect on ways they could be addressed. Key stakeholders were engaged to inform proposed responses. This updated consensus statement is the result. It does not establish new standards but outlines Aotearoa New Zealand's existing cultural, ethical, legal and regulatory requirements, and considers how these may be reasonably and feasibly met using some examples.

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MEDICAL/SURGICAL

Autonomy with responsibility: is informed consent just a signature on a paper? Evaluation in patients who underwent spine surgery

Jorge H. Nuñez Camarena, David Bosch Garcia, Berta Escudero

The Spine Journal, September 2023; 23(9)

Abstract

Background Context

Despite the relevance of informed consent in spine surgery, and all type of surgeries, and its daily use, there are very few studies that have checked if this document really accomplishes its duty.

Purpose

The aim of this study is to evaluate the real information that patients who went under spine surgery receive and know, after signing the informed consent.

Study Design/Setting

Retrospective study.

Patient Sample

Patients who underwent spine arthrodesis or spine discectomy between 2017 and 2019 were analyzed. Surgical technique and risks were explained before they were accepted to be on the surgery waiting list. They were given a copy of the informed consent.

Outcome Measures

Within the studied variables, we have asked patients if they have read the informed consent before surgery, if they could recall the surgical technique, spinal segment operated (cervical, thoracic, or lumbar) and vertebral levels operated. We added if they knew about surgical risks and if they looked for information about their procedure from other sources.

Methods

Answers were analyzed by age and educational level.

Results

From 458 total patients, only 51.9% of them answered all the questions. Also, 63% of patients agreed to have read the informed consent before surgery; 91.6% of patients knew about the spine segment operated; however, only 73.5% of patients remembered the surgical technique and 63.9% of patients could recall the vertebral levels. In addition, 39.1% of patients did not know about surgical risks and only 16.0% of patients mentioned to have looked for additional information using other sources. A significant statistical result was obtained between the search of additional information and younger patients ($p < 0.001$) and superior educational formation ($p = 0.023$).

Conclusions

Even though informed consent is an important procedure to get patients informed before spinal surgery, almost 40% of our patients underwent surgery without reading this document and not being aware of surgical risks.

Can we do it better? Consent in dentoalveolar surgery

Short Communication

Jai Parkash Ramchandani, Miss Alice Cameron, Montey Garg, Laurence Newman

British Journal of Oral and Maxillofacial Surgery, 19 August 2023

Open Access

Abstract

Obtaining informed consent is essential for any medical or dental procedure. Dentoalveolar surgery poses numerous risks due to the complex environment and anatomy of the oral cavity. Failure to seek and correctly document consent may lead to claims in negligence, as demonstrated by the increasing litigation in OMFS. We audited dentoalveolar surgery consent forms at two different UK OMFS units and found that many forms failed to document important material risks associated with procedures. In attempt to improve the consent process, we developed a standardised form containing a list of risks for dentoalveolar surgery that can be affixed to the consent form. We suggest other OMFS units adopt this form to standardise the consent process and optimise patient care while protecting clinicians from medico-legal claims.

Transformative experience and the principle of informed consent in medicine

Original Research

Karl Egerton, Helen Capitelli-McMahon

Synthese, 18 August 2023; 202(65)

Open Access

Abstract

This paper explores how transformative experience generates decision-making problems of particular seriousness in medical settings. Potentially transformative experiences are especially likely to be encountered in medicine, and the associated decisions are confronted jointly by patients and clinicians in the context of an imbalance of power and expertise. However in such scenarios the principle of informed consent, which plays a central role in guiding clinicians, is unequal to the task. We detail how the principle's assumptions about autonomy, rationality and information handle transformative experiences poorly, appealing to several difficult cases for medical decision-making to illustrate the resulting problem, and we consider how the existing literature on complications with consent fails to offer a resolution. We argue that recognition of the problem has a role to play in achieving a more effective response to transformative decisions. In Sect. 1 we introduce several representative cases of challenging patient decision-making that clinicians might face. In Sect. 2 we detail how transformative experience has been analysed in the recent literature, before outlining in Sect. 3 the theoretical basis of the principle of informed consent, which plays a central role in how clinicians are expected to support decision-making. In Sect. 4, having laid the groundwork for a clear description, we return to the cases given in Sect. 1 to confirm how their transformative nature presents a problem: either clinicians treat the decisions faced by these patients as 'normal', encouraging them to focus on information provision that patients may be unable to act on, or they treat them as transformative, in which case they lack the resources to recognise whether they are helping patients make (subjectively) good decisions. In Sect. 5 we argue that the existing literature does not offer any escape from this problem. We close in Sect. 6 by noting the significant impact that appreciating the problem of transformative experience could have on supporting transformative decisions in medicine and briefly suggesting how we might aim to develop new approaches to dealing with these.

Establishing an Ethics for Psychedelic Psychiatry

Brian Holoyda, Cameron Kiani

Psychiatric Services, 1 August 2023

Excerpt

…Informed consent, a cornerstone of ethical clinical practice, is particularly challenging in the context of psychedelic-assisted psychotherapy. The authors aptly point out that the potent effects of psychedelics necessitate an enhanced consent process to ensure understanding of risks and potential treatment outcomes. Patients should understand that acute and long-term emotional, cognitive, and perceptual changes may occur with psychedelic use. Although psychedelic journeys are positively transformative for many people, these journeys are not beneficial for everyone. Barber and Dike also note that psychedelics not only may be used to treat some mental disorders but also may lead to changes in personality and beliefs.

Eliciting such changes could be outside the scope of psychiatric treatment; therefore, practitioners need to ensure that their patients' understanding of the goals of treatment align with their own…

Ethical and Psychosocial Factors in the Decision-Making and Informed Consent Process for Upper Extremity Vascularized Composite Allotransplantation: A Mixed-Methods Study

Elisa J. Gordon, Jessica Gacki-Smith, Brianna R. Kuramitsu, Max Downey, Karen B. Vanterpool, Michelle J. Nordstrom, Tiffany Riggleman, Carisa M. Cooney, Sally Jensen, Gregory Dumanian, Scott Tintle, Macey Levan, Gerald Brandacher

Transplantation Direct, August 2023; 9(8)

Abstract

Background

Although upper extremity (UE) vascularized composite allotransplantation (VCA) aims to improve quality of life, relatively few have been performed worldwide to support evidence-based treatment and informed decision-making.

Methods

We qualitatively examined factors contributing to anticipated and actual decision-making about UE VCA and perceptions of the elements of informed consent among people with UE amputations, and UE VCA candidates, participants, and recipients through in-depth interviews. Thematic analysis was used to analyze qualitative data.

Results

Fifty individuals participated; most were male (78%) and had a mean age of 45 y and a unilateral amputation (84%). One-third (35%) were "a lot" or "completely" willing to pursue UE VCA. UE VCA decision-making themes included the utility of UE VCA, psychosocial impact of UE VCA and amputation on individuals' lives, altruism, and anticipated burden of UE VCA on lifestyle. Most respondents who underwent UE VCA evaluation (n = 8/10) perceived having no reasonable treatment alternatives. Generally, respondents (n = 50) recognized the potential for familial, societal, cultural, medical, and self-driven pressures to pursue UE VCA among individuals with amputations. Some (n = 9/50, 18%) reported personally feeling "a little," "somewhat," "a lot," or "completely" pressured to pursue UE VCA. Respondents recommended that individuals be informed about the option of UE VCA near the amputation date.

Conclusions

Our study identified psychosocial and other factors affecting decision-making about UE VCA, which should be addressed to enhance informed consent. Study participants' perceptions and preferences about UE VCA suggest re-examination of assumptions guiding the UE VCA clinical evaluation process.

Impacting Risk Communication: Educating Providers to Improve Informed Consent Conversations in Procedural Sedation

Book Chapter

Raquel M. Schears, Fernanda Bellolio

The New Science of Medicine, 25 July 2023; pp 237–249 [Springer]

Abstract

Patients that require procedural sedation (PS) in the emergency department (ED) are at risk of complications from emergency medical conditions that bring them to the ED plus the need for pain and anxiety management to successfully accomplish an intervention or diagnostic procedure. Explanation of the purpose, risks and benefits of PS is part of the informed consent. To participate in informed consent, patients need to understand what it is that they are agreeing to, and what are the risks and benefits of the procedure. Common challenges in these scenarios are that clinicians might not know the research evidence surrounding the risks and adverse events of the procedure, and present harms and benefits in general terms. Another challenge is that patients might not understand medical evidence when it is shared. To perform informed consent patients and providers need to actively participate sharing information and answering questions.

Patients must have sufficient information if they are to make decisions that reflect their own values and preferences, and physicians play a key role as educators in this process.

We identified a gap in our process of informed consent for PS. To fill this gap, we examined the prior literature to gain insight regarding incidence of adverse events in sedation when performed in the ED setting. Baseline provider knowledge was assessed with a pretest, thereafter didactic presentations on PS risks were provided and followed up with a posttest 6 months later. In the interim, we gave providers an evidence-based risk of adverse events card to facilitate informed consent conversations with patients undergoing PS in the ED. Because providers may find it difficult to strike a balance between too much and too little information, we also made a video on how to incorporate serious adverse events (SAEs) risks in an informed consent process for PS and made it available online for review.

Lastly, an evidence-based visual decision aid (DA) was developed out of a 3-round iterative process using a modified Delphi exercise, and created as an adjunct to supplement (rather than replace) clinician counselling about the spectrum of sedation risks for use by providers with identified patients. The visual aid became the focal point of the new informed consent process for PS implemented in 2017. The genesis of the DA, was based on PS survey feedback and patients and providers' perceptions of evidence-based audiovisual aids utility (study card, didactic presentation, informed consent simulation) judged to be helpful in communicating sedation risks, when obtaining consent in the ED.

Visual aids help to increase the knowledge of providers and patients when communicating the risks of procedures. Risks can be estimated and consistently reported by trained providers and can help engage patients in relevant risk conversation in routine practice. In other acute settings, DAs have been shown to improve information recall, have clear potential to alter patient experience and likely impact their perception of quality of care. The sustainability of ED provider-facilitated use of an evidence-based visual DA for PS with patients requires ongoing investigation. If interactive repetition builds on the value of evidence-based communication, then the impact of patient understanding regarding the risks of sedation may actually translate validity to the informed consent process.

Angiography Consent—Communicating Risk Versus Benefit

J. Reynolds, G. Armstrong, R. Newcombe, T. Wijohn

Heart Lung and Circulation, July 2023; 32(3)

Abstract

Background and Aim

To produce health health-literate patient resources takes a village! It requires many iterations, opinions and feedback from writers, experts and, most importantly, consumers. This poster focuses on the health literacy input, breaking down medical terminology and complex words, seeking consumer feedback and adding images, to enable wider comprehension whilst developing a resource aimed at patient education prior to the consent process for invasive coronary angiography.

Context

The proportion of adults in Australia and New Zealand with reading at levels one or two is similar, at around 44%, meaning they are likely to struggle to understand sufficient health information to make truly informed choices; further compounded in indigenous people and residents with English as a second language. Our Cardiology team at Te Whatu Ora-Waitemata and from the University of Auckland noted a gap at our hospitals; patients had limited access to cardiology staff in wards outside the Cardiology department and largely had no pre-procedural information prior to arriving at the cath lab and being consented.

Progress

We are developing an accessible resource for people awaiting angiography as in-patients, to be educated concerning the process and risks involved for this procedure from the referral time, to enable informed and meaningful consent. The team researched patient understanding of statistical presentation of risk; this will also be available at this meeting.

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GENERAL/OTHER

The language of consent: do we take or does the patient give?

Opinion
Simon M Everett
BMJ Endoscopy, 3 August 2023
Excerpt
… The other thing I hear frequently is how best to 'take consent'. Let us be clear, we cannot 'take consent'. The only action that deems consent to be legal is that it is 'freely given' and that is the basis on which we should talk to our patients. The patient gives us their consent and we receive it, but we do not take it.

Is this just pointless pedantry? Maybe, but if we are using words that describe the consent process incorrectly, it is likely that we are not allocating the time and space that this discussion requires. If we continue to use incorrect terminology, we will continue in the paternalistic way of thinking. Too often in medical practice consent is seen as a time- consuming barrier to doing the things that we believe to be best for our patients. Yes, it can be time consuming, but the more I avail patients of my time, the more I find they need it…

# # # #

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