Reimagining Informed Consent:
From Disclosure to Comprehension

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Reimagining Informed Consent

1. History of the doctrine of informed consent
2. Failure of the law to achieve ethical goals
3. A proposal
4. Starting to think about comprehension

Part I: What is Informed Consent?

Process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention

Source: AMA

What's the Purpose of Informed Consent?

- Protect individual autonomy
- Ensure human being status (respect for persons)
- Avoid fraud/duress
- Encourage good/rational decision making
- Involve public in medicine
- Improve patient care

Informed Consent History

- Paternalism
  - Non-maleficence

Informed Consent History

- Paternalism ➔ Autonomy
  - Non-maleficence ➔ Self-Determination

"The historic transition from the regime of 'doctor is right' to 'patient has rights'"

Sheldon F. Kurtz, *The Law of Informed Consent: From "Doctor is Right" to "Patient has Rights"*, 50 SYRACUSE L. REV. 1243 (2000)

Informed Consent History

- Paternalism ➔ Autonomy
- Battery ➔ Informed Consent (negligence)


POLL

Informed Consent: The Elements

1. Duty
2. Breach
3. Injury
4. Causation

Informed Consent History

- Paternalism ➔ Autonomy
- Battery ➔ Informed Consent (negligence)
- "Community" standard of disclosure ➔ "Reasonable Patient" standard of disclosure

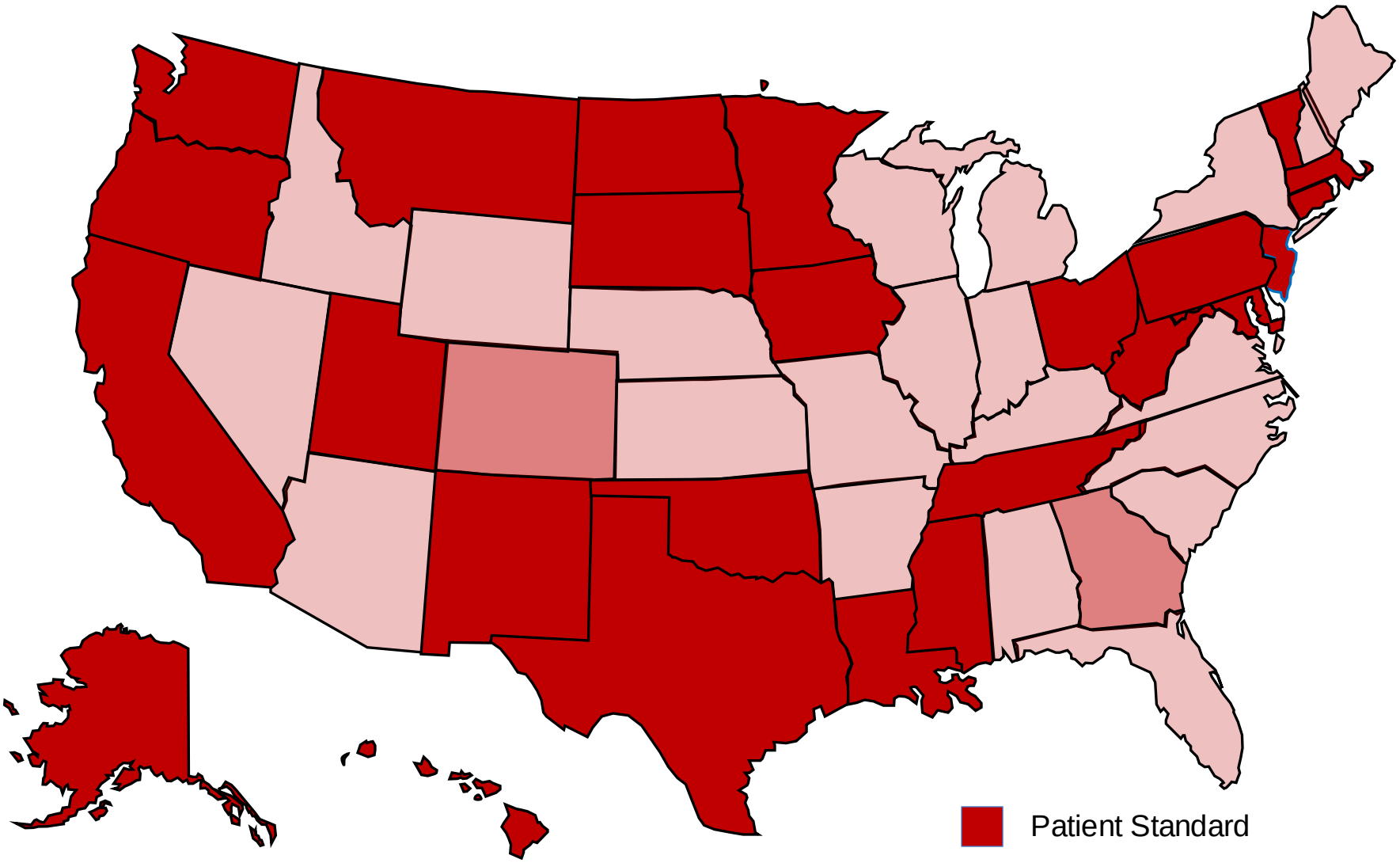
The *Canterbury* standard

- Requires disclosure of all information that is material to a reasoned decision by the patient to accept or reject the offered intervention
  - Degree and incidence of risk of intervention
  - Alternatives to intervention
  - Risks/benefits of no treatment
- Whether information is “material” determined by reasonable prudent person standard

Source: *Canterbury v. Spence*, 464 F. 772 (D.C. Cir. 1972)


POLL

Dueling Materiality Standards



Source: Studdert et al., *Geographic Variation in Informed Consent Law*, 4 J. Empirical Studies 103 (2007) (updated)

Dueling Materiality Standards

Community standard	Reasonable patient standard
Nature and scope of proposed treatment	Risks, benefits, and alternatives material to reasonable patient
Expert testimony re appropriate disclosure pursuant to professional standards	Expert testimony re risks of intervention, incidence, possibility that intervention caused resulting harm
Physician *discretion* to disclose	Physician *duty* to disclose
Decision to accept/reject therapy is *medical* decision	Decision to accept/reject therapy is *personal* decision

The Law Continues to Emphasize (and Expand) Disclosure

- *Hidding v. Williams,* 578 So. 2d 1192 (La. 1991) (physician's alcohol use is material to patient's decision) (*but see Kaskie v. Wright*, 589 A.2d 213 (Pa. 1991)

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- *Arato v. Avedon*, 858 P.2d 598 (Cal. 1993) (no mandated disclosure of life expectancy information)

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- *Arato v. Avedon*, 858 P.2d 598 (Cal. 1993) (no mandated disclosure of life expectancy information)

- *Faya v. Almarez*, 620 A.2d 327 (Md. 1993) (physician HIV+ status may be material to patient's decision)

The Law Continues to Emphasize (and Expand) Disclosure

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- *Arato v. Avedon*, 858 P.2d 598 (Cal. 1993) (no mandated disclosure of life expectancy information)

- *Faya v. Almarez*, 620 A.2d 327 (Md. 1993) (physician HIV+ status may be material to patient's decision)

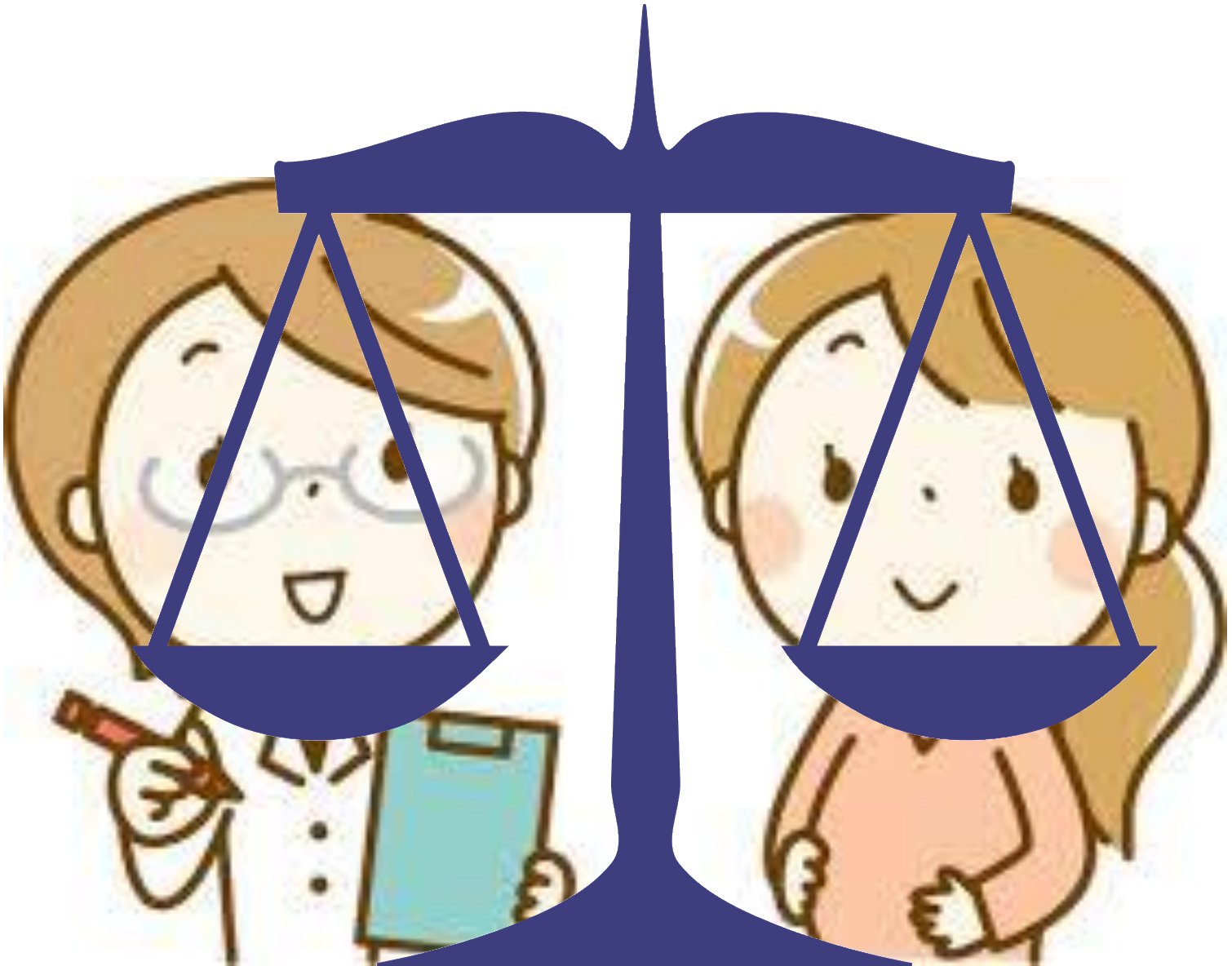
- *Johnson v. Kokemoor*, 545 NW 2d 495 (Wis. 1996) (physician's inexperience may be material to a patient's decision)

Part II: The Legal Doctrine Fails Patients

- "A superficial charade rather than an autonomous choice" (George Annas)
- "A charade, a symbolic but contentless formality" (Alexander Capron)
- The "bete noire of the medical malpractice doctrine" (Richard Shugrue & Kathryn Linstromberg)
- A "willing accomplice" to the subversion of informed consent (Grant Morris)
- "Ritualistic, formalistic, and hollow" (Peter Schuck)

Part II: The Legal Doctrine Fails Patients

Part II: The Legal Doctrine Fails Patients



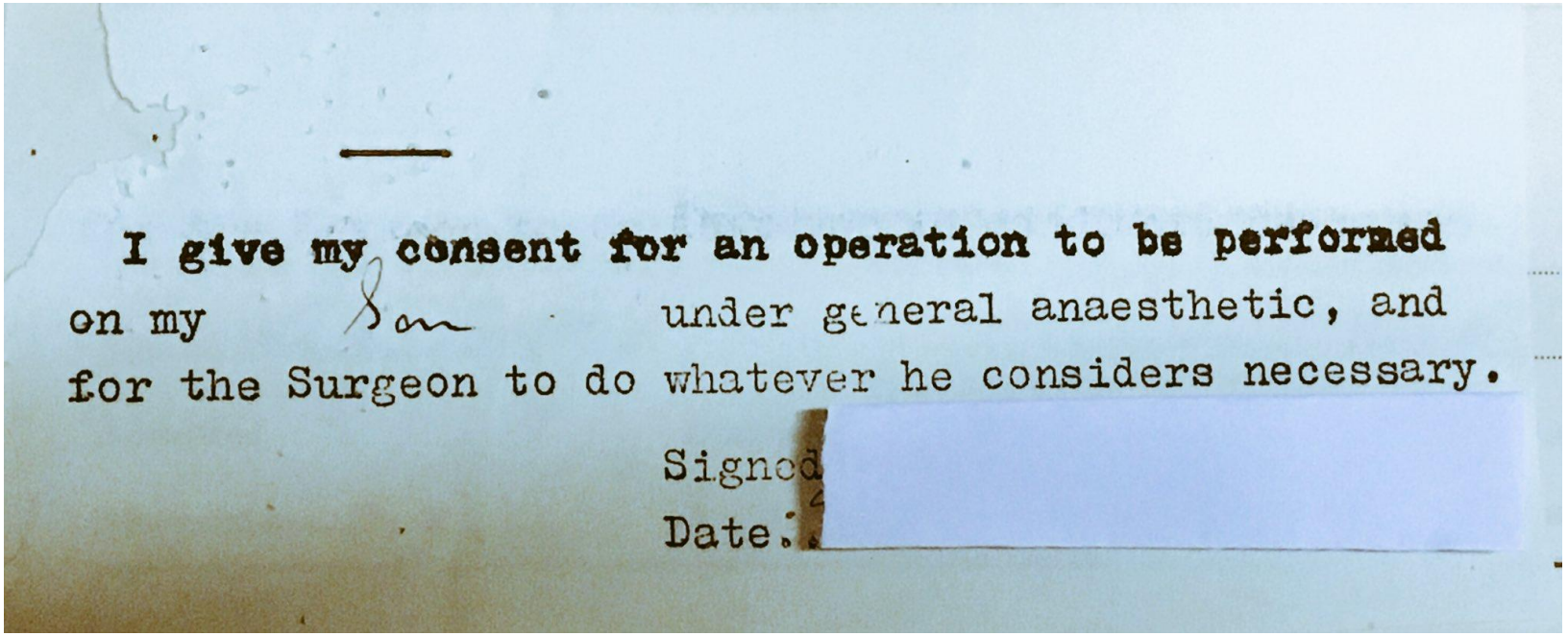
Canterbury Fails

All proposed solutions have focused on ***disclosures***, rather than on disclosures and ***comprehension***


POLL

The Legal Doctrine Fails Patients

Consent: 1954



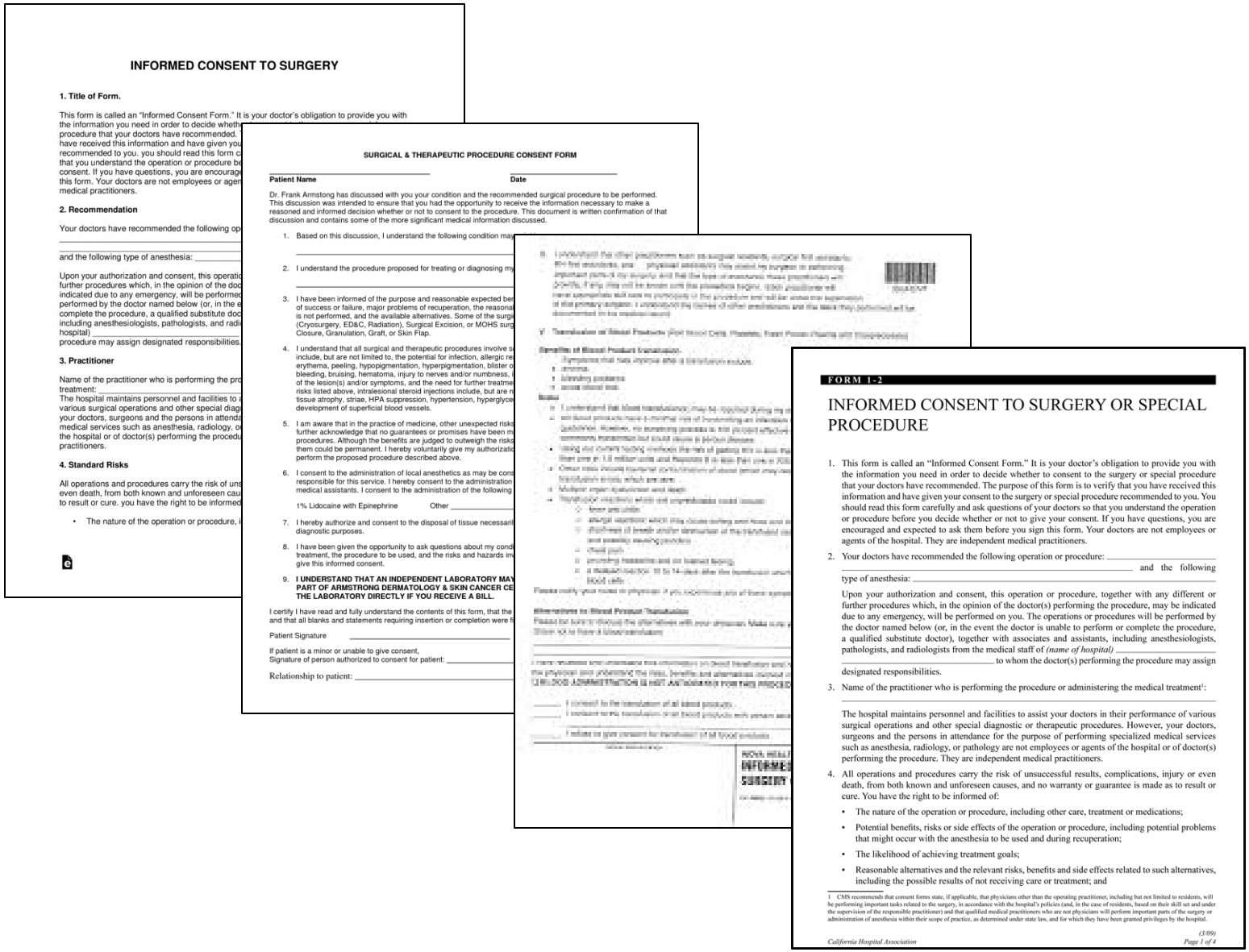
I give my consent for an operation to be performed
on my Son under general anaesthetic, and
for the Surgeon to do whatever he considers necessary.

Signed

Date:

Source: Gokani, Vinay (vimalgokani). "A real #consent form for #surgery from 1954, when the #NHS was an #infant. #HowThingsHaveChanged. #change #plasticsurgery #SoMe4Surgery #modern #history #informedconsent #PatientExperience #patientcenteredcare #patient #RT." 9 Oct. 2018, 6:49 a.m., Tweet.

Informed Consent: Now



INFORMED CONSENT TO SURGERY

1. Title of Form.

This form is called an "Informed Consent Form." It is your doctor's obligation to provide you with the information you need in order to decide whethe procedure that your doctors have recommended. have received this information and have given you recommended to you. you should read this form c that you understand the operation or procedure be consent. If you have questions, you are encourage this form. Your doctors are not employees or ager medical practitioners.

2. Recommendation

Your doctors have recommended the following op

and the following type of anesthesia:

Upon your authorization and consent, this operati further procedures which, in the opinion of the doc indicated due to any emergency, will be performe performed by the doctor named below (or, in the e complete the procedure, a qualified substitute doc including anesthesiologists, pathologists, and radi hospital) procedure may assign designated responsibilities.

3. Practitioner

Name of the practitioner who is performing the pr treatment:
The hospital maintains personnel and facilities to various surgical operations and other special diag your doctors, surgeons and the persons in attends medical services such as anesthesia, radiology, o the hospital or of doctor(s) performing the procedu practitioners.

4. Standard Risks

All operations and procedures carry the risk of uns even death, from both known and unforeseen cau to result or cure. you have the right to be informed

- The nature of the operation or procedure, i

SURGICAL & THERAPEUTIC PROCEDURE CONSENT FORM

Patient Name Date

Dr. Frank Armstong has discussed with you your condition and the recommended surgical procedure to be performed. This discussion was intended to ensure that you had the opportunity to receive the information necessary to make a reasoned and informed decision whether or not to consent to the procedure. This document is written confirmation of that discussion and contains some of the more significant medical information discussed.

1. Based on this discussion, I understand the following condition may
2. I understand the procedure proposed for treating or diagnosing my
3. I have been informed of the purpose and reasonable expected ben of success or failure, major problems of recuperation, the reasona is not performed, and the available alternatives. Some of the surgi (Cryosurgery, ED&C, Radiation), Surgical Excision, or MOHS surg Closure, Granulation, Graft, or Skin Flap.
4. I understand that all surgical and therapeutic procedures involve s include, but are not limited to, the potential for infection, allergic re erythema, peeling, hypopigmentation, hyperpigmentation, blister o bleeding, bruising, hematoma, injury to nerves and/or numbness, of the lesion(s) and/or symptoms, and the need for further treatme risks listed above, intralesional steroid injections include, but are n tissue atrophy, striae, HPA suppression, hypertension, hyperglyce development of superficial blood vessels.
5. I am aware that in the practice of medicine, other unexpected risks further acknowledge that no guarantees or promises have been m procedures. Although the benefits are judged to outweigh the risks them could be permanent. I hereby voluntarily give my authorizatio perform the proposed procedure described above.
6. I consent to the administration of local anesthetics as may be cons responsible for this service. I hereby consent to the administration medical assistants. I consent to the administration of the following

1% Lidocaine with Epinephrine Other

7. I hereby authorize and consent to the disposal of tissue necessari diagnostic purposes.
8. I have been given the opportunity to ask questions about my cond treatment, the procedure to be used, and the risks and hazards inv give this informed consent.
9. **I UNDERSTAND THAT AN INDEPENDENT LABORATORY MAY PART OF ARMSTRONG DERMATOLOGY & SKIN CANCER CE THE LABORATORY DIRECTLY IF YOU RECEIVE A BILL.**

I certify I have read and fully understand the contents of this form, that the and that all blanks and statements requiring insertion or completion were fi

Patient Signature

If patient is a minor or unable to give consent,
Signature of person authorized to consent for patient:

Relationship to patient:

FORM 1-2

INFORMED CONSENT TO SURGERY OR SPECIAL PROCEDURE

1. This form is called an "Informed Consent Form." It is your doctor's obligation to provide you with the information you need in order to decide whether to consent to the surgery or special procedure that your doctors have recommended. The purpose of this form is to verify that you have received this information and have given your consent to the surgery or special procedure recommended to you. You should read this form carefully and ask questions of your doctors so that you understand the operation or procedure before you decide whether or not to give your consent. If you have questions, you are encouraged and expected to ask them before you sign this form. Your doctors are not employees or agents of the hospital. They are independent medical practitioners.
2. Your doctors have recommended the following operation or procedure: _____ and the following type of anesthesia: _____

   Upon your authorization and consent, this operation or procedure, together with any different or further procedures which, in the opinion of the doctor(s) performing the procedure, may be indicated due to any emergency, will be performed on you. The operations or procedures will be performed by the doctor named below (or, in the event the doctor is unable to perform or complete the procedure, a qualified substitute doctor), together with associates and assistants, including anesthesiologists, pathologists, and radiologists from the medical staff of *(name of hospital)* _____ to whom the doctor(s) performing the procedure may assign designated responsibilities.
3. Name of the practitioner who is performing the procedure or administering the medical treatment[1]: _____

   The hospital maintains personnel and facilities to assist your doctors in their performance of various surgical operations and other special diagnostic or therapeutic procedures. However, your doctors, surgeons and the persons in attendance for the purpose of performing specialized medical services such as anesthesia, radiology, or pathology are not employees or agents of the hospital or of doctor(s) performing the procedure. They are independent medical practitioners.
4. All operations and procedures carry the risk of unsuccessful results, complications, injury or even death, from both known and unforeseen causes, and no warranty or guarantee is made as to result or cure. You have the right to be informed of:
   - The nature of the operation or procedure, including other care, treatment or medications;
   - Potential benefits, risks or side effects of the operation or procedure, including potential problems that might occur with the anesthesia to be used and during recuperation;
   - The likelihood of achieving treatment goals;
   - Reasonable alternatives and the relevant risks, benefits and side effects related to such alternatives, including the possible results of not receiving care or treatment; and

1 CMS recommends that consent forms state, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies (and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner) and that qualified medical practitioners who are not physicians will perform important parts of the surgery or administration of anesthesia within their scope of practice, as determined under state law, and for which they have been granted privileges by the hospital.

Canterbury Fails

"When we focus on the law, we tend to lose sight of the ethical underpinnings for it. In trying to focus on the 'letter of the law,' we often lose sight of its 'spirit.' When law becomes pervasive, we often forget about the original ethical questions that prompted the legal resolutions"

Charity Scott, *Why Law Pervades Medicine: An Essay on Ethics in Health Care*, 14 NOTRE DAME J.L. ETHICS & PUBLIC POL'Y 245 (2000).

…the legal doctrine of informed consent does not further the ethical goals upon which it is premised

Canterbury Fails

"'Overdisclosure' makes it difficult for patients to distinguish meaningful risks from trivial ones."

Robin Fretwell Wilson, *The Promise of Informed Consent*, THE OXFORD HANDBOOK OF U.S. HEALTHCARE LAW 229 (I. Glenn Cohen, Allison Hoffman, William M. Sage, & Kathleen G. Sebelius, eds. 2017)

"A significant body of research has demonstrated that the ideal of informed consent rarely matches the reality of healthcare decision making"

Megan Wright, *Resuscitating Consent*, 63 B.C. L. REV. 887, 900 (2021)

Patient Comprehension is Low

JB&JS THE JOURNAL OF BONE & JOINT SURGERY

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Prospective Evaluation of Patient Comprehension of Informed Consent

Crepeau, Allison E. MD[1]; McKinney, Bart I. MD[2]; Fox-Ryvicker, Maya RPA-C[1]; Castelli, Jennifer RPA-C[1]; Penna, James MD[1]; Wang, Edward D. MD[1]

Author Information

The Journal of Bone & Joint Surgery: October 5, 2011 - Volume 93 - Issue 19 - p e114
doi: 10.2106/JBJS.J.01325

BUY SDC Metrics

Abstract

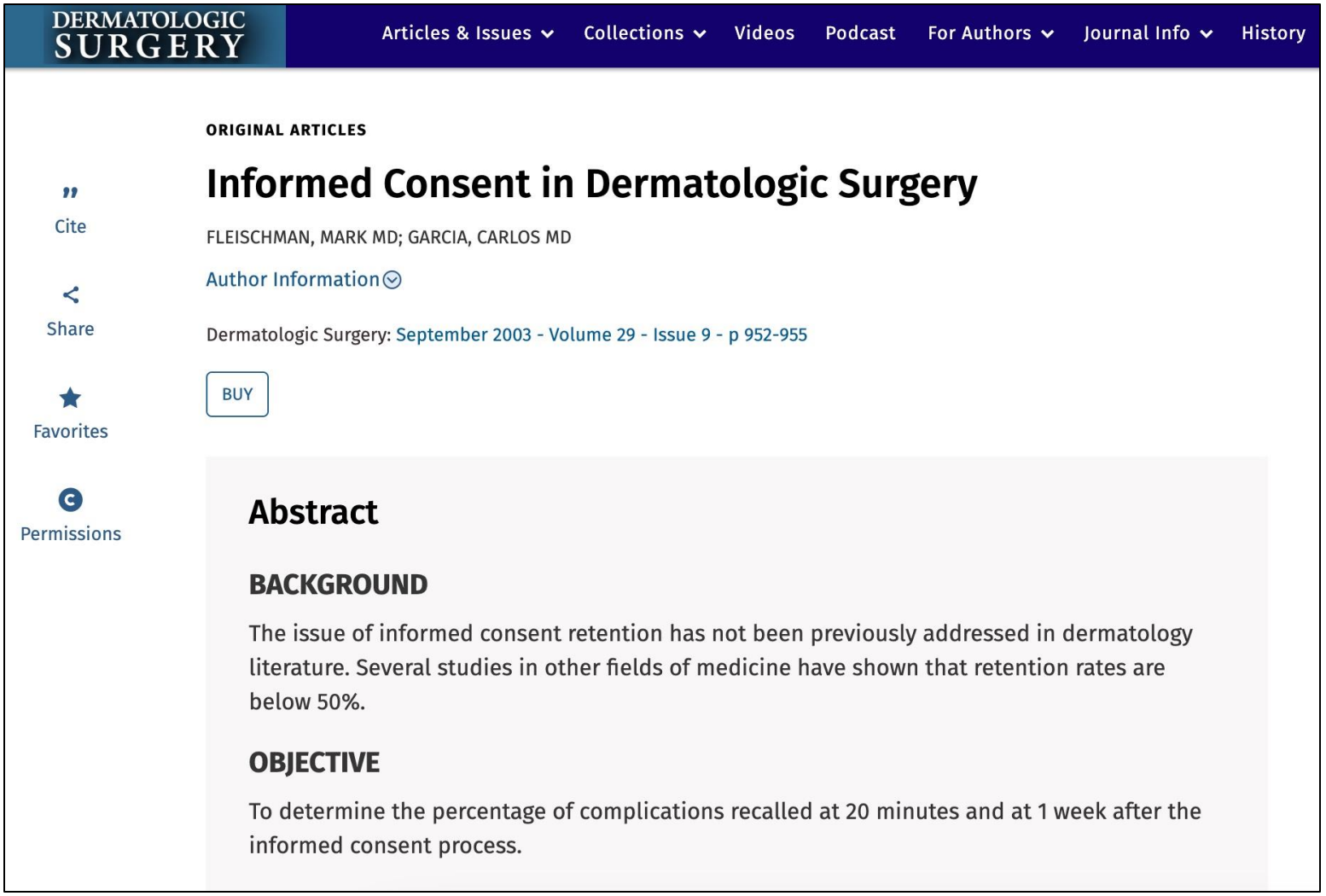
Background:

Physicians and society may overestimate the level of patient comprehe
process of obtaining informed consent for medical and surgical treatme
study was to prospectively measure the immediate level of patient com
that surgical consent is obtained and the effect of time on this level of

"Patient comprehension and recall immediately following a thorough discussion of the consent form was unexpectedly low"

Source: Allison E. Crepeau, Bart I. McKinney, Maya Fox-Ryvicker, Jennifer Castlli, James Penna, & Edward Wang, *Prospective Evaluation of Patient Comprehension of Informed Consent*, 93(19) J. BONE & JOINT SURGERY e114(1) (2011)

Patient Comprehension is Low



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ORIGINAL ARTICLES

Informed Consent in Dermatologic Surgery

FLEISCHMAN, MARK MD; GARCIA, CARLOS MD

Author Information

Dermatologic Surgery: September 2003 - Volume 29 - Issue 9 - p 952-955

BUY

Abstract

BACKGROUND

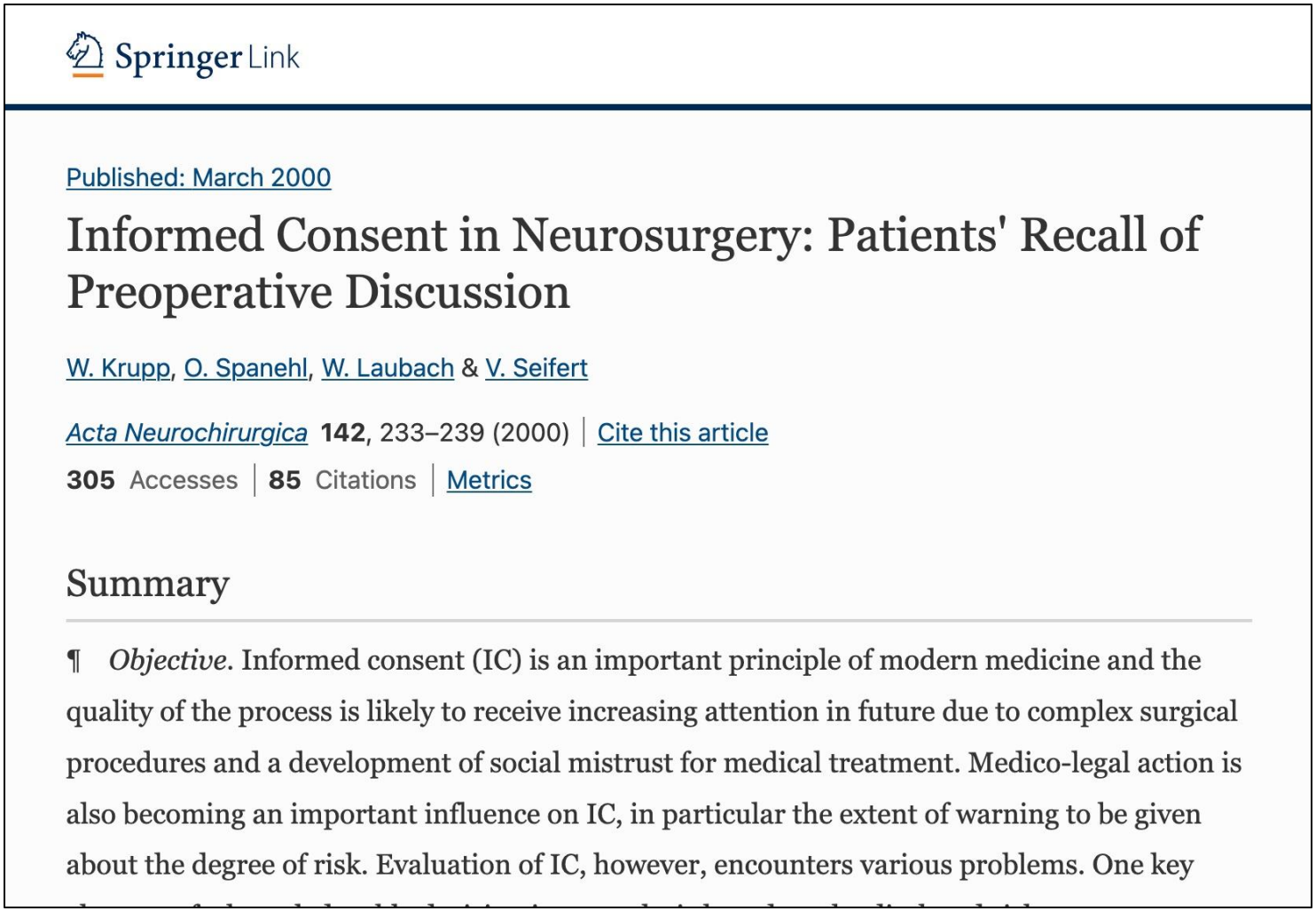
The issue of informed consent retention has not been previously addressed in dermatology literature. Several studies in other fields of medicine have shown that retention rates are below 50%.

OBJECTIVE

To determine the percentage of complications recalled at 20 minutes and at 1 week after the informed consent process.

Source: Mark Fleischman & Carlos Garcia, *Informed Consent in Dermatologic Surgery*, 29(9) DERMATOLOGICAL SURGERY 952 (2003)

Patient Comprehension is Low



Springer Link

Published: March 2000

Informed Consent in Neurosurgery: Patients' Recall of Preoperative Discussion

W. Krupp, O. Spanehl, W. Laubach & V. Seifert

Acta Neurochirurgica **142**, 233–239 (2000) | Cite this article

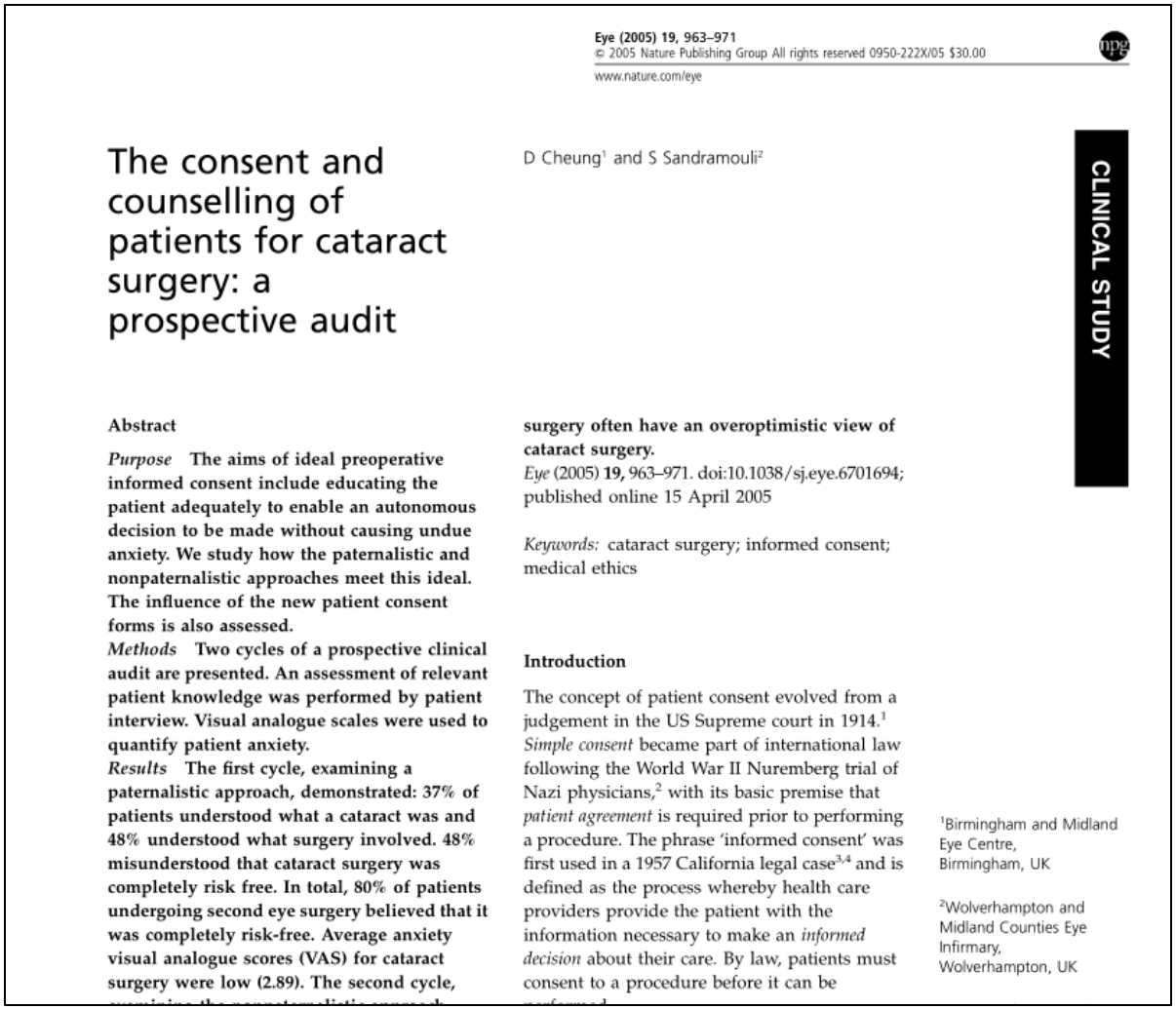
305 Accesses | **85** Citations | Metrics

Summary

¶ *Objective*. Informed consent (IC) is an important principle of modern medicine and the quality of the process is likely to receive increasing attention in future due to complex surgical procedures and a development of social mistrust for medical treatment. Medico-legal action is also becoming an important influence on IC, in particular the extent of warning to be given about the degree of risk. Evaluation of IC, however, encounters various problems. One key

Source: Wolfgang Krupp, Oliver Spanehl, Wilfried Laubach, & V. Seifert, *Informed Consent in Neurosurgery: Patients' Recall of Preoperative Discussion*, 142 ACTA NEUROCHIRURGICA 233 (2000)

Patient Comprehension is Low



Eye (2005) 19, 963–971

www.nature.com/eye

CLINICAL STUDY

The consent and counselling of patients for cataract surgery: a prospective audit

D Cheung[1] and S Sandramouli[2]

Abstract

Purpose **The aims of ideal preoperative informed consent include educating the patient adequately to enable an autonomous decision to be made without causing undue anxiety. We study how the paternalistic and nonpaternalistic approaches meet this ideal. The influence of the new patient consent forms is also assessed.**

Methods **Two cycles of a prospective clinical audit are presented. An assessment of relevant patient knowledge was performed by patient interview. Visual analogue scales were used to quantify patient anxiety.**

Results **The first cycle, examining a paternalistic approach, demonstrated: 37% of patients understood what a cataract was and 48% understood what surgery involved. 48% misunderstood that cataract surgery was completely risk free. In total, 80% of patients undergoing second eye surgery believed that it was completely risk-free. Average anxiety visual analogue scores (VAS) for cataract surgery were low (2.89). The second cycle,**

surgery often have an overoptimistic view of cataract surgery.

Eye (2005) **19,** 963–971. doi:10.1038/sj.eye.6701694; published online 15 April 2005

Keywords: cataract surgery; informed consent; medical ethics

Introduction

The concept of patient consent evolved from a judgement in the US Supreme court in 1914.[1] *Simple consent* became part of international law following the World War II Nuremberg trial of Nazi physicians,[2] with its basic premise that *patient agreement* is required prior to performing a procedure. The phrase 'informed consent' was first used in a 1957 California legal case[3,4] and is defined as the process whereby health care providers provide the patient with the information necessary to make an *informed decision* about their care. By law, patients must consent to a procedure before it can be

[1]Birmingham and Midland Eye Centre, Birmingham, UK

[2]Wolverhampton and Midland Counties Eye Infirmary, Wolverhampton, UK

Source: Dennis Cheung & Soupramanien Sandramouli, *The Consent and Counselling of Patients for Cataract Surgery*, 19(9) EYE (LOND) 963 (2005)

Part III: A Proposal

A legal doctrine of informed consent that emphasizes both disclosures (objective) and patient comprehension (subjective)

Informed Consent: The Elements (a Proposal)

1. Duty
   - Physician Disclosure (objective)
   - Patient comprehension (subjective)
2. Breach
3. Injury
4. Causation

Part IV: Thinking about Comprehension

Approaches to Assuring Comprehension:

Part IV: Thinking about Comprehension

Approaches to Assuring Comprehension:

- Patient decision aids

Part IV: Thinking about Comprehension

Approaches to Assuring Comprehension:

- Patient decision aids
- Technological tools

Part IV: Thinking about Comprehension

Approaches to Assuring Comprehension:

- Patient decision aids
- Technological tools
- “Repeat-back” techniques

Repeat-back

Predictors of Comprehension during Surgical Informed Consent

Aaron S Fink, MD, FACS, Allan V Prochazka, MD, MSc, William G Henderson, PhD, Debra Bartenfeld, RN, MSN, Carsie Nyirenda, MB, ChB, MPH, Alexandra Webb, MD, FACS, David H Berger, MD, MHCM, FACS, Kamal Itani, MD, FACS, Thomas Whitehill, MD, FACS, James Edwards, MD, FACS, Mark Wilson, MD, PhD, FACS, Cynthia Karsonovich, MD, FACS, Patricia Parmelee, PhD

BACKGROUND: Patient comprehension during surgical informed consent remains problematic. Using data from our randomized trial of methods to improve informed consent comprehension, we performed an additional analysis to define independent factors associated with improved patient understanding.

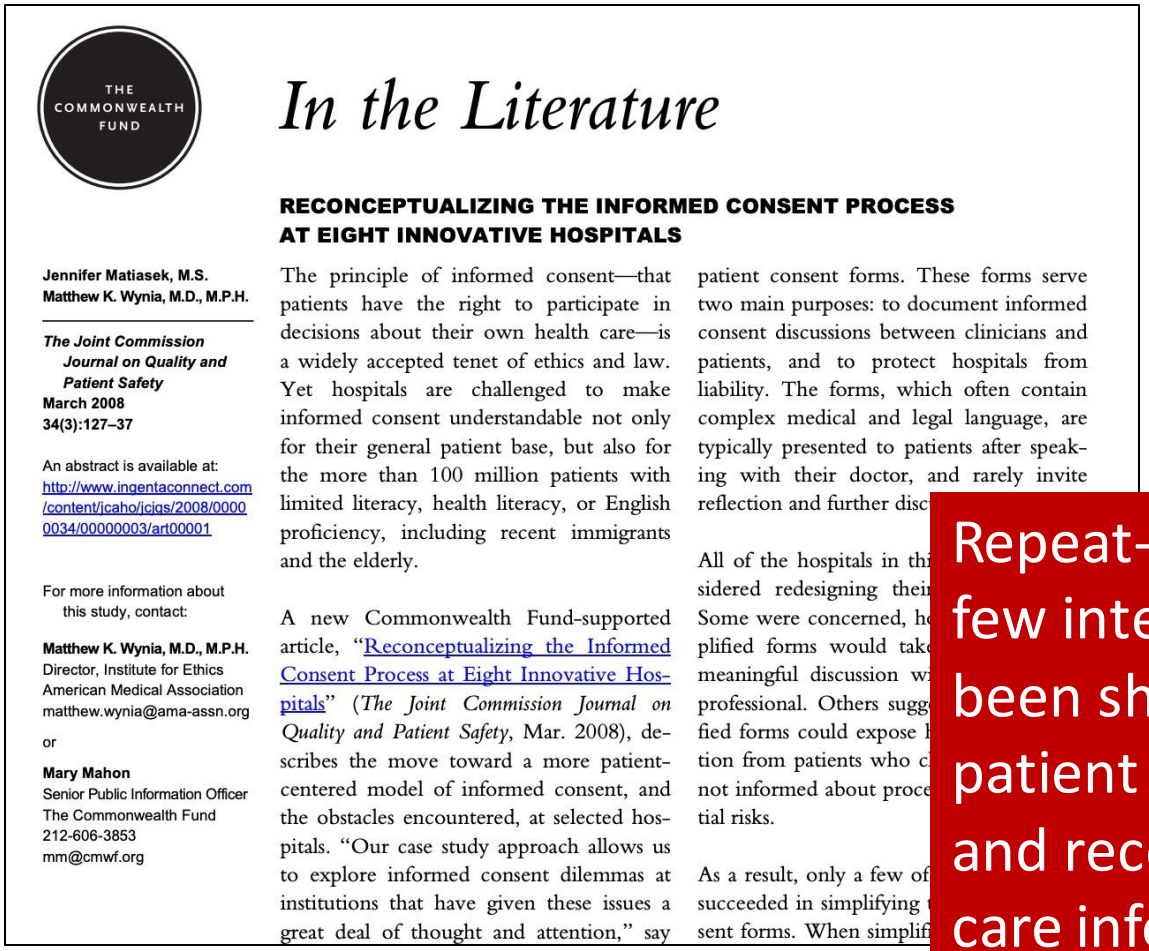
STUDY DESIGN: Patients scheduled for 1 of 4 elective operations (total hip arthroplasty [n = 137], carotid endarterectomy [n = 178], laparoscopic cholecystectomy [n = 179], or radical prostatectomy [n = 81]) at 7 Department of Veterans Affairs (VA) medical centers were enrolled. All informed consent discussions were performed using iMedConsent (Dialog Medical), the VA's computerized informed consent platform. Using a unique module within iMedConsent, we randomized patients to repeat back (RB), requiring correct reiteration of procedure-specific facts, or standard (STD) iMedConsent. Patient comprehension was tested after the informed consent discussion using procedure-specific questionnaires. Time spent completing the informed consent process was measured using time stamps within iMedConsent. Multiple linear regression identified factors independently associated with improved comprehension.

RESULTS: We enrolled 575 patients (276 RB, 299 standard); 93% were male, 74% were Caucasian, and 89% had at least a high school education. Independent factors associated with improved comprehension included race ($p < 0.01$), ethnicity ($p < 0.05$), age ($p < 0.02$), operation type ($p < 0.01$), group assignment ($\pm$ RB; $p < 0.05$), and total consent time ($p < 0.0001$). Patient comprehension was maximized when informed consent took between 15 and 30 minutes. RB's positive impact on patient comprehension was weaker in the analysis including consent time.

CONCLUSIONS: Comprehension during informed consent discussions may be limited in individuals with potential language difficulty due to ethnicity or education. Total consent time was the strongest predictor of patient comprehension. Affording adequate time for informed consent discussions and using informed consent adjuncts such as RB may enhance comprehension in such individuals. (J Am Coll

Source: Aaron S. Fink, Allan V. Prochazka, William G. Henderson, Debra Bartenfeld, Carsie Nyirenda, Alexandra Webb, David H. Berger, Kamal Itani, Thomas Whitehall, James Edwards, Mark Wilson, Cynthia Karsonovich, & Patricia Parmelee, *Predictors of Comprehension During Surgical Informed Consent*, 210(6) J. AM. COLL. SURGEONS 919 (2010)

Repeat-back



THE COMMONWEALTH FUND

In the Literature

RECONCEPTUALIZING THE INFORMED CONSENT PROCESS AT EIGHT INNOVATIVE HOSPITALS

Jennifer Matiasek, M.S.
Matthew K. Wynia, M.D., M.P.H.

The Joint Commission Journal on Quality and Patient Safety
March 2008
34(3):127–37

An abstract is available at:
http://www.ingentaconnect.com/content/jcaho/jcjqs/2008/00000034/00000003/art00001

For more information about this study, contact:

Matthew K. Wynia, M.D., M.P.H.
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The principle of informed consent—that patients have the right to participate in decisions about their own health care—is a widely accepted tenet of ethics and law. Yet hospitals are challenged to make informed consent understandable not only for their general patient base, but also for the more than 100 million patients with limited literacy, health literacy, or English proficiency, including recent immigrants and the elderly.

A new Commonwealth Fund-supported article, "Reconceptualizing the Informed Consent Process at Eight Innovative Hospitals" (*The Joint Commission Journal on Quality and Patient Safety*, Mar. 2008), describes the move toward a more patient-centered model of informed consent, and the obstacles encountered, at selected hospitals. "Our case study approach allows us to explore informed consent dilemmas at institutions that have given these issues a great deal of thought and attention," say

patient consent forms. These forms serve two main purposes: to document informed consent discussions between clinicians and patients, and to protect hospitals from liability. The forms, which often contain complex medical and legal language, are typically presented to patients after speaking with their doctor, and rarely invite reflection and further disc

All of the hospitals in thi
sidered redesigning their
Some were concerned, h
plified forms would take
meaningful discussion wi
professional. Others sugg
fied forms could expose h
tion from patients who c
not informed about proce
tial risks.

As a result, only a few of
succeeded in simplifying t
sent forms. When simplifi

Repeat-back is "one of the few interventions that has been shown to improve patient comprehension and recollection of health care information"

Source: Jennifer Matiasek & Matthew K. Wynia, *Reconceptualizing the Informed Consent Process at Eight Innovation Hospitals*, 34(3) THE JOINT COMMISSION ON QUALITY AND PATIENT SAFETY, THE COMMONWEALTH FUND 127, 128 (2008)

Part IV: Thinking about Comprehension

Approaches to Assuring Comprehension:

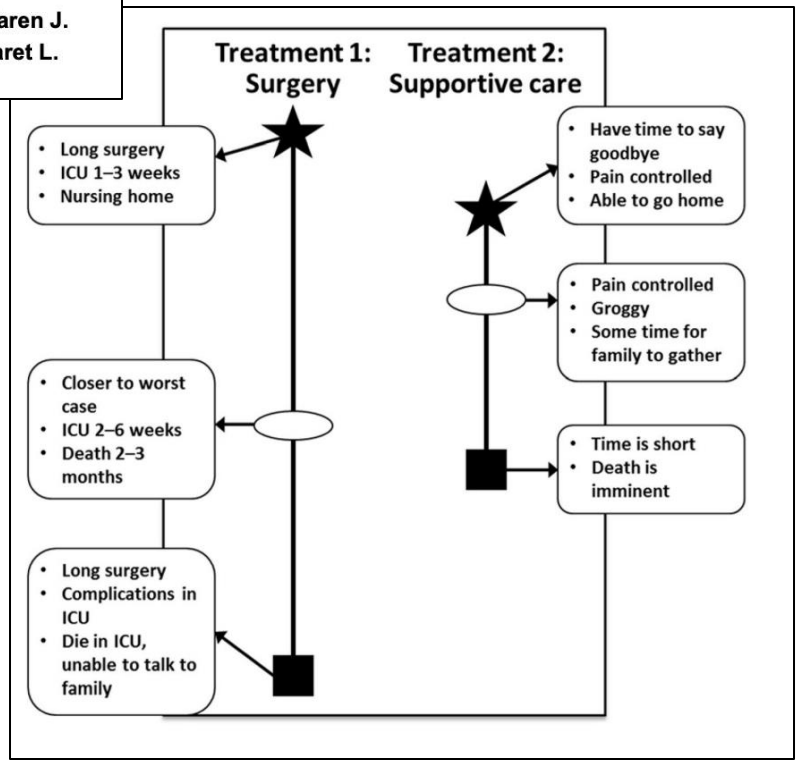
- Patient decision aids
- Technological tools
- “Repeat-back” techniques
- “Best case/worst case” approach

Best case/Worst case

J Am Geriatr Soc. 2015 September ; 63(9): 1805–1811. doi:10.1111/jgs.13615.

"Best Case/Worst Case": Qualitative evaluation of a novel communication tool for difficult in-the-moment surgical decisions

Jacqueline M. Kruser, MD[1], **Michael J. Nabozny, MD**[2], **Nicole M. Steffens, MPH**[2], **Karen J. Brasel, MD, MPH**[3], **Toby C. Campbell, MD**[4], **Martha E. Gaines, JD, LLM**[5], and **Margaret L. Schwarze, MD, MPP**[2,6]



Source: Jacqueline M. Kruser, Michael J. Nabozny, Nicole M. Steffens, Karen J. Brasel, Toby C. Campbell, Martha E. Gaines, & Margaret L. Schwarze, *"Best-Case/Worst Case": Qualitative Evaluation of a Novel Communication Tool for Difficult in-the-Moment Surgical Decisions*, 63(9) J. AM. Geriatr. Soc. 1805 (2015)

Some Additional Thoughts…

- Recognize inequities in education, race, and age

Some Additional Thoughts…

- Recognize inequities in education, race, and age
- Legislation versus common law

Some Additional Thoughts…

- Recognize inequities in education, race, and age
- Legislation versus common law
- Delegation of informed consent

Thank you!

Valerie Gutmann Koch, JD
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