

RISK, SAFETY, QUALITY NEWS & REVIEWS

SAFE START MEDICAL –

By Richard Vazquez MD, FACS – CEO, SafeStart Medical, Inc.



Informed Consent Perversions: When Compliance Prevails Over Communication

“When compliance prevails over communication, consent loses its value.”

Informed consent was never meant to be a legal shield — it was intended as a conversation of trust. Yet in too many facilities, the process has devolved into paperwork that satisfies administrators more than it informs patients.

The Purpose of Informed Consent

At its core, informed consent is about *educating and empowering* the patient. It ensures that patients understand the **risks, benefits, alternatives, and possible complications** of a planned procedure — in language they can actually comprehend.

But somewhere along the way, compliance checklists replaced meaningful dialogue. The focus shifted from *informing* the patient to *documenting* that a form was signed.

! When Policy Replaces Understanding

1 The Blue-Ink Rule

A hospital instituted a policy requiring surgeons to sign consent forms in the preoperative area *with blue ink* to prevent surgeon truancy in the preop area. The intent was good — to confirm the surgeon’s physical presence. But the rule soon became the goal itself. The color of the ink mattered more than whether the patient actually understood the procedure.

2 The Nurse-Written Consent

In many institutions, nurses — not surgeons — complete the consent form. The patient’s “discussion” becomes a checkbox exercise. The form reads correctly, but the *conversation with the surgeon may have never happened*.

3 The Deferred Discussion

Sometimes the conversation occurs late or not at all, with staff assuming the surgeon has already spoken with the patient. The patient signs anyway, reassured that “the doctor will explain everything before surgery.”

By the time the patient is on the gurney on the way into the operating room, it’s too late for questions.

When Compliance Prevails

Administrative systems value predictability and uniform documentation — but *medicine depends on mutual understanding*.

The more we chase flawless compliance, the easier it becomes to mistake the appearance of consent for the reality of informed choice.

How SafeStart Preserves Information Integrity

While SafeStart doesn’t digitize the consent process itself, it helps preserve its *purpose*.

By capturing a clear image of the signed consent form — showing the patient’s name, procedure, and surgical site — SafeStart ensures that documentation reflects genuine, verified decisions.

But SafeStart goes further. It **augments the consent process** by continuously sharing the entire document set among all stakeholders — including the most important one: the patient (or family/guardian). This continuous, shared visibility allows every team member to review the same record, from intake to the operating room.

Through **repetitive review by multiple sets of eyes**, SafeStart safeguards the internal consistency of the information — across forms, checklists, key images, and photographs.

The goal isn’t more paperwork.

It’s transparency: to share information clearly and continuously so there is no question that what’s documented is exactly what was discussed and planned.



The Rise of Video Informed Consent

Recent commentary from the **American Society for Healthcare Risk Management (ASHRM)** highlights a growing movement toward **video-based informed consent** — an approach that complements written and verbal discussions rather than replaces them.

Our nurse adviser, **Katherine Lee, DNP, RN, CPHRM, CMPE**, brought this timely development to our attention. According to a recent **ASHRM podcast**, video and multimedia education can enhance patient understanding, increase satisfaction, and significantly reduce malpractice risk.

Attorney **Bruce Keplinger**, a defense lawyer with more than forty years of experience, noted that a signed form is often only partial proof of consent — patients may recall just 25% of what was discussed verbally.

Dr. Ankur Patel of the American Society of Pain and Neuroscience described video informed consent as a “game-changer,” enabling patients to truly understand risks, benefits, and alternatives before agreeing to treatment.



Listen: [*ASHRM Podcast – Video Informed Consent: Enhancing Patient Understanding and Satisfaction, Reducing Malpractice Risk*](#)
(Access may be restricted to ASHRM members.)

A West Coast surgeon, **Shawn Steen, MD**, founded **VIDOCEO**, an innovative company that enables clinicians to assemble patient-specific informed consent videos from a large library of animated procedural clips. Templates can be saved, customized, and reused to improve consistency and patient comprehension.



Watch a brief physician walkthrough:
[Provider Walkthrough – VIDOCEO](#)

A Future Direction for SafeStart

Several years ago, I proposed to our **SafeStart investors — most of them surgeons** — that we eventually include a **video-informed consent option** in the SafeStart workflow. At the time, many thought the idea was too forward-looking and that clinicians and risk managers might resist recording such discussions.

Today, with clinicians already using mobile devices for SafeStart intake, the timing is right. We plan to design a **secure, optional iOS feature** that allows authorized users to record a video informed consent directly within the SafeStart app.

- The video would be stored **securely on our cloud server**, and the **original could not be edited** by anyone.
- **Updates or appended videos** could be added when warranted — for example, if new clinical information arose or the surgical plan changed.
- **Patients could view these recordings** through their portal at any time.

- All versions would be **archived, not deleted**, maintaining a complete **audit trail** for compliance and risk management purposes.

The goal, as always, is transparency, continuity, and mutual understanding — the true purpose of informed consent.

Closing Reflection

“When compliance prevails over communication, consent loses its value.”

The challenge for healthcare leaders is not to eliminate forms, but to ensure they *remain servants of understanding, not substitutes for it*.

Call to Action

 **Schedule a brief demo:** info@safestartmedical.com

 **Watch:** [The Checklist Paradox – YouTube Explainer](#)

 **Join the conversation:** Have you seen consent practices that lost their purpose? Share your experience — respectfully — in the comments.

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