Consent 201: Varying Scenarios

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Consent 201: A Potpourri of Issues

- Homeless Discharge
- Interstate Adoption
- Scope of Practice Issues
- Police/DA Access to Medical Records Related to Identity Theft
- Privacy Rights of the Deceased
- Attorney Rights with a Minor
- Serial Consent
- Informed Consent
- Patient Belongings Examination
Homeless Discharge (cont. from this morning)

- In order to standardize the level of discharge planning service hospitals provide, California Legislature passed, and the Governor signed SB 1152.
- The law took effect January 1, 2019.
- Purpose is to help prepare the homeless patient for return to the community by connecting him or her with available community resources, treatment, shelter and other supportive services.
- The law does not require hospitals to find or create services that do not exist in the community.
- Documented compliance with elements of this legislation are required effective January 1, 2019.
Services That Must be Offered Before Discharge

- Physician examination and determination of stability for discharge
- Referral for follow up care
- Referral for behavioral health care if it’s determined that the patient requires behavioral health care
- Food
- Weather appropriate clothing
- Discharge medications (prescription)
- Infectious disease screening
- Vaccinations appropriate to the presenting medical condition
- Transportation within 30 minutes or 30 miles of the hospital
- Screening for and assistance to enroll in affordable health insurance coverage
Patient admitted to the unit

RN assesses for housing status. Is the patient homeless?

NO

Care provided per standard of care.

YES

SW consult placed.

SW consult completed, and elements of SB 1152 are documented in the Homeless Patient Discharge Smart Form, in combination with CM support.

No SW available

SW not available (nights/weekends), and pt is stable for discharge. RN completes elements of CB 1152 and documents in the Homeless Patient Discharge Smart Form.

**Required Discharge elements**: 
1. A post-discharge destination will be identified for each patient, this may be: 
   a. A social services agency, nonprofit social services provider or governmental services provider that has agreed to accept the patient. 
   b. The homeless patient’s “residence” 
   c. An Alternative destination, as indicated by the homeless patient. 
2. Referrals for necessary follow-up care, both medical and behavioral, as determined by the treating provider. 
3. A meal, unless medically contraindicated. 
4. Weather appropriate clothing will be offered and provided. 
5. If determined by the provider, and the outpatient pharmacy is available, discharge medications will be provided. Otherwise a written prescription will be provided if applicable. 
6. Patient will be offered transportation to their chosen destination, if that destination is within 30 miles or 30 minutes. 
7. Compliance with the homeless patient discharge planning policy will be documented in the electronic medical record.

**Please reference the Adult Discharge Planning Policy (Appendix A).**

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Create a Form in Your Medical Record
Make it Easily Visible for Staff

The discharge plan is intended to help prepare the patient for return to the community by connecting him or her with available community resources, treatment, shelter, and other supportive services. The plan must be guided by the patient's best interests, physical and mental condition, and preferences for placement. The patient must be informed of placement options. The available community options for this patient are:

VS.

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### Homeless Discharge

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<table>
<thead>
<tr>
<th>Discharge Destination</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social services agencies, nonprofit social services providers, and/or government agencies</td>
<td></td>
</tr>
<tr>
<td>Any location the patient identifies as his/her principal dwelling place</td>
<td></td>
</tr>
<tr>
<td>Any other desired discharge destination indicated by patient or their representative</td>
<td></td>
</tr>
<tr>
<td>Patient declined to state where he/she will go after discharge</td>
<td></td>
</tr>
</tbody>
</table>

### Discharge Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transportation</td>
<td>transport provided</td>
</tr>
<tr>
<td></td>
<td>patient declined offer of transport</td>
</tr>
<tr>
<td></td>
<td>transport not offered due to distance</td>
</tr>
<tr>
<td></td>
<td>transport not offered since patient declined to state destination</td>
</tr>
<tr>
<td>Meal</td>
<td>meal provided</td>
</tr>
<tr>
<td></td>
<td>meal medically contraindicated</td>
</tr>
<tr>
<td></td>
<td>patient declined offer of meal</td>
</tr>
<tr>
<td>Clothing</td>
<td>patient’s clothing adequate for weather</td>
</tr>
<tr>
<td></td>
<td>weather-appropriate clothing provided</td>
</tr>
<tr>
<td></td>
<td>patient declined offer of weather-appropriate clothing</td>
</tr>
<tr>
<td>Medications</td>
<td>appropriate supply of all necessary medications provided</td>
</tr>
<tr>
<td></td>
<td>only prescription provided</td>
</tr>
<tr>
<td></td>
<td>no medications prescribed</td>
</tr>
<tr>
<td></td>
<td>patient declined offer of prescription and medications</td>
</tr>
</tbody>
</table>

### Follow-up Care

The physician or designee must communicate post-discharge medical needs to the patient. The person who communicated post-discharge medical needs to the patient was:

**Physician/Designee Name:**

The patient was given a medical screening exam and evaluation, and the physician has determined:

**Follow-up Behavioral Health Care**

- [ ] is needed
- [ ] is NOT needed
Put the List of Resources in Your Discharge Summary or After Visit Summary, “AVS”

- A comprehensive list of San Francisco County Community Resources can be provided to the patient by doing one of the following:
  - Utilize the dot phrase “.sfhelp” in the discharge instructions within the AVS
  - Go to www.freeprintshop.org and print out the appropriate community resource list.
Interstate Adoption: Releasing Sarah

- You are contacted by L&D about Sarah who is to be adopted, but there is no “legal” paperwork in the chart.
- Biological Mother, Maria, presents you with a few pages entitled “birth-adoption plan” from a Texas adoption agency.
Who Can Take Sarah Home?

- The document is dated from a few days prior, is not witnessed or notarized.
- Birth Mother Maria has said that she wants nothing to do with Sarah and won’t make any decisions for the child.
- The Texas Agency paperwork identifies prospective adoptive parents, The Smiths.
- A portion of the document authorizes the named adopting parents or 3rd party to provide consent.
Is Maria Being Coerced to Give up Her Baby?

- Your nurses and staff are slightly nervous about Maria. We want to make sure that she is giving up Sarah of her own free will. Consider:
  - Why is she here, not in Texas?
  - Is she a victim of some sort of forced surrogacy?
  - Does she understand? Make sure you review with an interpreter using Social Work, Spiritual Services
  - Who will protect her rights?
Baby Sarah Wants to Go “Home”

Are the Texas agency papers valid to allow the identified “parents,” The Smiths, to take the child from the hospital while the adoption is finalized and who can consent for the child?
What are the Rules for Adoption Across State Lines?

• In 1960, The Interstate Compact on the Placement of Children (ICPC) was established, and it establishes procedures for ensuring the safety and stability of placements of children across state lines

  » See Family Code 7900 et seq.
What are the Rules?

Family Code § 7907.5 (b) states:

• A child who is born in this state and placed for adoption with a person who is not a resident of this state is subject to the provisions of the ICPC, regardless of whether the adoption petition is filed in this state. In interstate placements, this state shall be deemed the sending state for any child born in the state.
California Requirements for Interstate Adoption Consent

• Both the birth parents and the prospective adoptive parents must have representation for the adoption, whether it is an attorney or an adoption agency
  » See Fam. Code §§ 8801.3; 8814; 8700; 8606.5

• Consent for the adoption cannot be given until after the birth of the child and mother is discharged from the hospital
  » See Fam. Code §§ 8801.3, 8606.5
California Requirements for Interstate Adoption Consent (cont.)

- For a **direct placement**, consent must take place in the presence of an adoption service provider or other delegated agent who has advised the parents of their rights.
- In an **agency adoption**, a form is signed before two witnesses and acknowledged before an official of the agency.

  » See Fam. Code §§ 8801.3; 8814; 8700; 8606.5
How Can we Release the Baby if the Adoption Isn’t Final?

• To release baby from the hospital to prospective parents requires Form AD22 be completed and signed by all parties

• The completed AD22 is given to the birth parents, the prospective adoptive parents, and is submitted to the California Dept. Public Health

  » See Health and Safety Code § 1283
AD22

- AD22 is used for all adoptions to allow for decision making for the child and release while the adoption is pending.
Whew!! Are we Done Yet???

- It’s Friday and you think that you have finished helping Sarah find a home
- On Saturday, you get paged: The Smiths are NOT coming and have backed out of the Adoption — meanwhile, the baby’s name has been changed to “Smith” in the EHR!!! The Texas adoption agency has found another family, The Jones’ and they are on their way?
- The process begins again — make Sarah anonymous in your record
- And, by the way, have you upped your security for Sarah?
Interstate Adoption Resources

• http://icpcstatepages.org/california/info

• https://www.childwelfare.gov/topics/systemwide/laws-policies/statutes/consent/
Scope of Practice Issues

- California has a shortage of healthcare professionals; this was made more acute by the Affordable Care Act that opened the door to healthcare for more people.

- See, e.g., Times of San Diego, February 8, 2019 Editorial Opinion, “A Shortage of Health Care Workers Is California’s Next Crisis”

Scope of Practice and Expansion of Workforce Efforts

- For the past several years we have seen efforts to expand the workforce, licensure categories or scope of practice, e.g.:
  - Board of Behavioral Sciences – began licensing LPCC’s (Licensed Professional Clinical Counselors) – effective January 1, 2010
  - MFT interns and trainees allowed to provide counseling via telehealth and Medi-Cal reimbursement for MFTs in FQHCs or Rural Health Clinics in 2016
  - Mental health intervention training for police officers and first responders in 2016
New Laws From Last Year

• LPCCs and Associate Professional Clinical Counselors (APCCs) eligible for education loan grant money in California (AB 1188)

• MFTs and LPCCs authorized to be second signer on W&I Code § 5250 Notice of Certification for mental health involuntary two-week holds (AB 191)

• NPs and PAs cannot be restricted from ordering or furnishing buprenorphine if done in compliance with federal Comprehensive Addiction and Recovery Act (SB 554)
Expansion

• Implementation of the Prop 56 Medi-Cal Physicians and Dentists Loan Repayment Act to provide financial assistance on student loans to qualifying recently graduated doctors and dentists who agree to serve Medi-Cal beneficiaries in underserved areas (SB 849)

• Medical Board of California - no longer allowed to automatically disqualify an applicant with a prior conviction more than seven years old (AB 2138)
This Year, More Expansion

• Medical Lab Technicians’ scope of practice expanded to permit them to perform microscopic urinalysis, most blood smear reviews, and automated ABO/Rh testing (AB 2281)

• CNA teaching programs - students can complete the 60-hour pre-certification classroom training online; and, any licensed vocational nurse (LVN) or registered nurse (RN) with at least two years’ of experience that includes at least one year working with chronically ill or elderly patients, can teach in-person CNA classes (AB 2850)
How About Nurse Practices in your Dermatology Clinic?

- During a Joint Commission Survey they are talking to an LVN in your dermatology clinic (it’s on your hospital license)
- The Clinic is very busy and successful and they have developed some “efficiencies” that include LVN’s doing “subq” injections of a local anesthetic
- The Joint doesn’t think the LVN is working within her scope
- The Clinic suggests continuing this with a protocol — other places do it!!
- Regulatory agrees and tells the surveyor that the practice will stop and a citation is avoided
- Was the Joint Commission correct?
California Regulations 16 CCR Section 2518.5

“An LVN can perform technical and manual skills which include the following:

• (a) Uses and practices basic assessment (data collection), participates in planning, executes interventions in accordance with the care plan or treatment plan and contributes to evaluation of individual interventions …

• Provides direct patient care as described in (a)

• Administers medications … ”

• Thus, injection of local anesthetic requires more knowledge of anatomy than basic assessment skills
Identity Theft

• In 2003, the World Privacy Forum estimated the number of victims of identity theft to be between 250,000 and 500,000.

• In 2013, estimate was 1.84 million victims.

• This is an increase of 21 percent.

• Average cost to the victims: $18,660.

• Medical Identity Theft is under reported.

• https://oag.ca.gov/sites/all/files/agweb/pdfs/privacy/medical_id_theft_recommend.pdf
What is Medical Identity Theft?

The fraudulent use of an individual’s identifying information in a health care setting to obtain medical services or goods, or for financial gain; victims may be individuals, providers or payors.
Patient Suspected of Identity Theft … How Much Can You Help Law Enforcement?

- Patient is picked up by law enforcement after being found wandering on the streets … she appears confused, and claims to not know where she lives.
Identity Theft

- On presentation to the ED, nursing locates identification in her purse, and the patient confirms that she is **Inez Innocence**

- She is admitted to the hospital under that name and she signs the terms and conditions of admission, “Inez Innocence”

- “Inez” signs six different surgical/procedural consents and is in the ICU for a week
Inez may not Really be “Innocent”

- Multiple identification cards are found in her purse
- “Inez” stays in the hospital for two weeks and undergoes multiple evaluations by specialty providers including psychiatry
- At one point, a nurse offers to contact her next of kin and Inez insists that she will do the contacting
- A keen social worker finds Inez’s mother, and calls to tell her of her daughter’s admission
Inez Who???

- Inez’s mother is surprised because she had just talked to Inez, who is at work that day.
- The Social Work writes a note: “attempted to locate family, many irregularities, will speak to physician.”
- Risk is called and the Police are brought in.
- The Police do their thing and find out that “Inez”s real name is Georgia Grifter.
- “Inez” continues to claim that that she is Inez.
Does it sometimes feel like working in a hospital is like living in a movie, almost every day?
Will the Real Inez, Please Stand Up?

Now I am really dating myself!!
The Damage

- Ultimately, it is determined that the Georgia generated $750,000 in hospital bills, all in the name of Inez and in Inez’s medical record

- Georgia is signed up for Medi-Cal and signs a new Terms and Conditions, using her real name “Georgia Grifter”

- Social work, in talking with the real Inez, learns that Inez’s life has been in the state of disarray since her identity was stolen

- Georgia tells the Social Worker, Liz that she and others target people in bars by distracting them and stealing their purse … they pick people who sort of look like Georgia
What Happens During a Criminal Case for a Crime Committed on Your Premises?

- The District Attorney’s Office contacts you and asks for your help to prosecute this case of identity theft — your hospital made the police report; you are the victim along with the real Inez
- But to show evidence of the crime, they need access to information from the medical record
Consent Needed?

Do you need the patient’s consent to disclose PHI to the District Attorney?
Who is the Patient?

- In this case, it is Inez Innocence!!!
- She is the victim here
- She would have the right to see her medical record!!
- How could Georgia object!!!
- Providers worry that this is a HIPPA violation. But See California Attorney General article
  www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/
Cooperation with Law Enforcement
45 CFR § 164.512

- 45 CFR § 164.512 - Uses and disclosure of PHI for which an authorization, or opportunity to agree or object, is not required

(a) Uses and disclosures required by law.

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.
Cooperation with Law Enforcement

(c) Disclosures about victims of abuse, neglect or domestic violence

(e) Disclosures for judicial and administrative proceedings

(f) Disclosures for law enforcement purposes.

A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.
Cooperation with Law Enforcement (cont.)

(f)(1) *Pursuant to process and as otherwise required by law.*
  - i.e. reportable wounds/injuries, court order, warrant, subpoena

(f)(2) *Limited information for identification and location purposes.*
  - i.e. to identify or locate suspect, fugitive, material witness or missing person

(f)(3) *Victims of a crime*
  - i.e. when law enforcement seeks information about a victim or suspected victim of crime
Cooperation with Law Enforcement (cont.)

(f)(4) **Decedents**
- i.e. to advise law enforcement about a suspicious death suspected to be the result of criminal activity

(f)(5) **Crime on premises**
A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity

(f)(6) **Reporting crime in emergencies**
Cooperation with Law Enforcement (cont.)

(g) *Uses and disclosures about decedents*

- i.e. to provide information to assist coroners and medical examiners for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law

So …

- You’ve determined that you may be able to help out the DA because your facility was the victim of this crime (45 CFR § 164.512(f)(6))

- **But how much information can you disclose?**
Does the “Minimum Necessary Apply in This Case”?

45 CFR § 164.502(b)- **Minimum necessary standard:**

When using or disclosing protected health information or when requesting protected health information from another covered entity or business associate, a covered entity or business associate **must make reasonable efforts to limit protected health information to the minimum necessary** to accomplish the intended purpose of the use, disclosure, or request.
Does Minimum Necessary Apply?

- 45 CFR § 164.502(b)(2) lists exceptions to the minimum necessary standard.

**Minimum necessary does not apply to:**

v. uses or disclosures that are required by law, as described by 45 CFR § 164.512(a)
But Wait … What About California Law? — There Has to be a Way

• California law is more stringent: CMIA: Civil Code section 56.10 (a) et. seq.
  • Need authorization — Inez has given it
  • Or is it a mandated report for elder or dependent adult abuse, or child abuse? This would be disclosure required by law
  • See Penal Code section 1543
  • Investigation of Medi-Cal fraud — does this allow disclosure?

**Best Practice** … disclose only the minimum necessary until there is subpoena power
Working with the District Attorney

• Don’t assume they know what they need — they will say, “I want everything” — at this stage, there have been no criminal charges, no subpoena power

• Working with them, they needed to show evidence of the intent to commit a crime, the capacity to commit a crime and statements evidencing state of mind

• They don’t need the whole record. What is relevant?
  • Signed consent forms before and after identity
  • Basic medical condition and what medications on board
  • Statements to social work and other evidencing continuing attempt to defraud and commit a crime
California Statute Violations

- W & I Code section 14014 and 14107: False declaration as to eligibility and false claim
- Penal Code section 487: Grand Theft
- Penal Code section 550(a) (5): False writing & false claim
- Penal Code section 550 (a) (7): knowingly submitting a claim for a health care benefit which was not used by or on behalf of claimant
Privacy Rights of the Deceased

- Bobby Bigbucks was a high flying member of the community with huge business acumen and just a whole lot of money
- At one point late in his life in 2011, he sought help from Dr. Less, your physician expert on memory and aging — the tests showed substantial decline
- Bobby had many wives, many children. He died in 2017
Bobby’s Last Wishes

- Sometime in the last three years of his life, Bobby’s current wife, Melanie, arranged for him to change his very complex estate, which allowed her to disinherit Bobby’s children
- There is a will contest
- Medical Records of Bobby have been obtained by the parties, including Bobby’s son who is the plaintiff in the lawsuit
- Bobby’s attorney, Elina, wants to speak with Dr. Less
- She says:
  - Deceased people have no privacy rights
  - She has the records, so Dr. Less can talk to her
  - In this type of litigation, there is no privilege
Dr. Less

- Dr. Less is certain that Bobby had to be out of it
- He also has many unkind things to say about Melanie — she didn’t care about Bobby and all she wanted was his money
- Bobby’s relationship with his kids was complex
- Would you want Bobby to discuss this with the attorney?
Privacy Rights of the Deceased

- Patients have the same privacy rights in death as they do when they are living — at least for 50 years

- “Protected health information excludes individually identifiable information … regarding a person who has been deceased for more than 50 years”
  
  - 45 CFR 160.103 (2) (iv)

- An authorization for records may be valid if signed by the beneficiary or personal representative of a deceased patient
  
  - Civil Code section 56.11 (c) (4)
But This is a Will Contest

• Elina cites:
  • Evidence Code section 1000: “there is no privilege under this section as to a communication relevant to an issue between parties all of whom claim through a deceased patient, regardless of whether the claims are by testate or intestate succession or by inter vivos transactions”
  • Evidence Code section 1002: no privilege as to communications as to patient’s intent with respect to a will or other writings
  • Evidence Code section 1019: no psychotherapist-patient privilege in a will contest
What will MD’s be Asked in Will Contests?

• Testamentary capacity: did the patient have it?
• Was the patient being unduly influenced
• What medications was the patient taking?
• What does the physician know about the psycho-social situation
• Best Practice: have Dr. Less give his testimony to both parties in a deposition
Ex Parte Communications with Physicians

• What are the rules about physicians having ex parte communications with defense or patient attorneys
  • Plaintiffs attorneys think they are “entitled”
  • Defense attorneys would love to be allowed access under the concept of “efficiency” and “litigation”
• The *Torres* case precludes ex parte discussions in most situations to avoid an improper violation of the physician patient privilege

➢ *Torres vs. Superior Court* (1990) 221 Cal App 3rd 181
Attorneys Rights Related to Minors

• Three year old Jessie has “short gut syndrome” but her parents believe that her fevers just relate to her teething.

• Despite repeated instructions, visits to the home and several near death experiences because her parents have not complied with instructions to bring her to the hospital as soon as she gets even a low grade fever, CPS did not act on your reports.
Attorneys Rights Related to Minors (cont.)

- Until Jessie became septic. Now CPS is acting
- The child is with a foster parent
- There is also now a contested custody battle; one parent is blaming the other for neglect
- The Court has asked for an evaluator and appointed an attorney for the child
- The evaluator and attorney call your physician to start the process
- Can your staff talk to them?
- Under both HIPAA and CMIA, yes
Family Code Section 3118: Evaluators

- The evaluator is usually a psychologist, but not always. They have broad authority, but the Court may define the scope. They can speak to:
  - Child welfare agency
  - Law enforcement
  - Review results of multidisciplinary child interview
  - Review summary of a written report from any therapist or other professionals
  - Request a forensic medical examination
  - Review medical records and obtain medical information
- They make recommendations to the Court
What About the Child’s Attorney?

The attorney is usually an investigator of the facts and has an attorney-client relationship with the child. Courts will appoint counsel in cases involving:

- Neglect or abuse
- Contested child custody proceedings
- Adoptions
- Termination of parental rights
- Juvenile court proceedings
Family Code Section 3151: Child’s Attorney

The attorney stands in the “shoes” or “booties” of the child to:

- Investigate
- Participate in court proceedings
- **Obtain all relevant records and have contact with providers:**
  - medical records ... mental health professionals, school records
- Request hearings
- Present evidence
- Ascertain wishes of child
- Make recommendations to the court
Serial Consent

- There are several situations where patients are receiving a series of treatments that require consent, e.g.
  - Chemotherapy
  - Blood transfusions
  - Radiation treatment
  - Lumbar punctures related to Bone Marrow Transplant
- Your providers have met and documented the requirements for informed consent — do they need a new form every time?
For Blood Transfusions — Sample Policy

- When and how often to obtain consent for transfusion:
  a. Hospitalized patient: consents obtained using forms described in ___are valid for the length of the patient’s admission, unless the patient or a surrogate withdraws consent.
  b. Outpatient: Once per year for outpatients undergoing medical procedures that require continued, ongoing transfusion therapy
How Long is a Consent Good? Policy

• Duration of consent form validity: a consent form is valid as long as the patient’s condition does not change and the surgery or procedure remains the same. Special care should be taken to review those consents that were obtained more than one month prior to the proposed surgery or procedure.

• However, there are no strict rules governing how far in advance of the procedure a consent discussion can or should occur.

• As a general rule, however, the discussion should occur with sufficient time allowed for the patient to consider his/her decision. Several weeks may not be unreasonable, provided the patient's condition has not changed, and the nature of the risks and benefits remains the same.
How Long is a Consent Form Good for?

- Common sense, reasonableness and good judgment should dictate whether the patient's consent is timely in any given circumstance.
- If there have been changes in the indication for the procedure, the risks, the alternatives or the likelihood of success, a new consent must be obtained.
- If there is any doubt, the patient should be given as much information as necessary in order to obtain informed consent prior to beginning the procedure.
Several Courses of Treatments Over Weeks or Months

- There is no legal prohibition against having one consent form state that a specific number of courses of chemotherapy or treatment will be given — consent for the treatment plan

- The form can state the number of treatments and/or dates of treatment (although this could change based on scheduling so be careful)

- Make sure the form is reviewed every time and noted in the chart

- Does your medical record allow this?

- If patient’s clinical condition has changed such that the risk has changed, then it should be noted
Informed Refusal: Are we Meeting our Obligations?

TJC’s goal of the informed consent process:

- “Obtaining informed consent presents an opportunity to establish a mutual understanding between the patient and the licensed independent practitioner or other licensed practitioners with privileges about the care, treatment and services that the patient will receive.
- Informed consent is not merely a signed document. It is a process that considers patient needs and preferences, compliance with law and regulation and patient education. Utilizing the informed consent process helps the patient to participate fully in decisions about his or her care, treatment and services.”

*Standard RI.01.03.01 (2019)*
Joint Commission: Elements of Performance
RI.03.01

• The informed consent process includes a discussion about the following:
  • The patient's proposed care, treatment, and services
  • Potential benefits, risks, and side effects of the patient's proposed care, treatment, and services
  • The likelihood of the patient achieving his or her goals
  • And any potential problems that might occur during recuperation
It Also Includes Informed Refusal

• Reasonable alternatives to the patient's proposed care, treatment, and services. The discussion encompasses risks, benefits, and side effects related to the alternatives and the **risks related to not receiving the proposed care, treatment, and services.**
CMS Guidelines

- The Conditions of Participation (CoP) Interpretive Guidelines state that material risks could include:
  - Risks with a high degree of likelihood but a low degree of severity,
  - As well as risks with a very low degree of likelihood but high degree of severity
  - Probable consequence of declining recommended or alternative therapies

  42 CFR 482.51 (b) (2)
CMS: Interpretive Guidelines: Section 42 CFR 482.51 (b)(2)

- Policy for informed consent must cover the following:
  - Who may obtain the patient’s consent (which providers)
  - Which procedures require informed consent
  - Circumstances for no consent (emergent circumstances)
  - Circumstances for when a patient’s representative may provide consent
  - Content of the form and instructions for completing it
  - The process used to obtain informed consent, including how informed consent is to be documented in the medical record
Case Law

- That information which MD should know would be considered significant by a reasonable person in the patient’s position
- Supplemented by patient’s unique concerns/condition (as know or should be known by MD)
- Discuss potential consequences of refusal

The OB World: Why is Documentation of All Care and Efforts to Gain Patient Cooperation so Important?

- There is a significantly longer statute of limitations in OB birth injury cases for children — years and years. Providers will not independently remember what they did.
- The damages in birth injury cases are often huge.
- There are often lengthy periods of labor, spanning multiple shifts of nurses, residents, attendings, midwives.
- Hand offs are often not documented — how does the strip look over time?
- Even though Medicine says that Fetal Heart Monitoring strips are not “evidence based,” it can be the make or break part of a case.
OB: A High Risk Area

- Hospitals appropriately assign the task of informed consent/informed refusal to the physicians
- But with expanding scope of practice and increased involvement of Certified Nurse Midwives, NP’s and others, the risk of failure for informed refusal is widespread
- And when there is a birth injury case, EVERYONE is involved in the lawsuit
Refusal of C-Section?

- Patient and husband presented to medical center at 6:45 a.m. with a one-page birth plan, desiring
  - Natural birth
  - Intermittent fetal monitoring, and
  - Avoidance of interventions
- 5:30 shift change: first team told 2nd team that patient “adamantly did not want a C-section.” No documentation
- No documented discussion with patient by new MD or team about C-section
- All providers, (nurses and MDs) agree that there was extensive discussion with the patient — she denies
Refusal of C-Section

- After periods of prolonged decelerations, baby was delivered at 8:19 p.m. with thick meconium and without respiratory effort
- Apgar scores were 2, 4, 6. HIE, cooling
- Baby discharged November 13 with NG tube and phenobarbital for seizures
- Claim:
  - Failure to perform C-section by 6 pm.
  - Negligent starting of Pitocin
  - Negligence by 2nd team in not discussing or offering C-section — no documentation
  - Lack of informed refusal for C-section
What Does a Birth Injured Child Look Like at Age Five or Six? – Let’s Look at a Recent Description

• Alice is five years old and lives with her family. Their home is not suited to raising a child with disabilities
• Alice is unable to move with any intent and can do nothing for herself
• She cannot walk or crawl, or hold herself up into a sitting position
• Alice cannot hold her head up; she is fed with a G-tube
• Alice cries or whines and smiles occasionally. She recognizes her parents and turns her face toward voices
• She has intractable seizures — five to six per day
• Alice’s injuries have had a devastating impact on not just one life but also of those of her parents and siblings
What Does an Informed Refusal Look Like in the OB Context?

• A mother to be has the right to make decisions about her own body, including the refusal of a C-section or other interventions

• But WHAT do we tell her about the risks? Having a birth injured child will have a devastating impact on the mother

• Do our clinicians have the framework of knowing how to describe the risks of refusal?

• It is as much about the consequences to the mother (who has rights) as it is to the child (who at this point has no rights)
Informed Refusal

• Arguments made by OB’s and Midwives against giving all this detail
  • It is “coercive”
  • Child birth is natural and this is a very rare event
  • It isn’t “patient centered care”
  • It is the woman’s body

• Is this approach really recognizing the rights of a woman in labor, or is it being paternalistic?

• Does this approach meet the legal requirements?
Example of L & D Time Line - Could it be More Detailed?

<table>
<thead>
<tr>
<th>Labor</th>
<th>Vitals</th>
<th>Medication Rate/Dose Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Heart Rate: 67 (Device Time: 01:55:50)</td>
<td>oxytocin in 0.9 % sodium chloride (PITOCIN) 40 unit/1000 mL infusion - Dose: 6 milli-units/min; Rate: 9 mL/hr; Route: Intravenous; Scheduled Time: 0150</td>
</tr>
<tr>
<td>Labor</td>
<td>BP: 128/64 (Device Time: 01:52:07)</td>
<td>*Interventions: (provider at bedside)</td>
</tr>
<tr>
<td>Labor</td>
<td>Labor Response: Pushing with contractions</td>
<td>Provider Notification</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Provider Name/Title:</td>
</tr>
<tr>
<td>Labor</td>
<td></td>
<td>Notification Reason: Other (comment) (at bedside)</td>
</tr>
<tr>
<td>Labor</td>
<td>Labor pain</td>
<td>Pain Assessment: 0-10</td>
</tr>
<tr>
<td>Labor</td>
<td>Labor Response: Pushing with contractions</td>
<td>Pain Interventions</td>
</tr>
</tbody>
</table>

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Is There Opportunity for More Detail?

Give the record the benefit of the team’s thinking. 5-6 years later, no one will remember what was going on
Birth Plan: No Episiotomy

- During labor, patient had deep transverse arrest and persistent OP position despite attempted rotation with deterioration in the EFM strips and relatively high station.

- An OB note documented that they would let her continue to try and push and then would reassess her station after about 30 min.

- An operative delivery was felt to be likely via forceps versus doing a cesarean.

- After more prolonged pushing, the patient was counseled on operative vaginal delivery and chose to have delivery via forceps.

- The forceps delivery was done WITHOUT episiotomy and the patient suffered a very severe 4th degree perineal laceration.

- **Poor documentation about discussion of risks of forceps, option of doing a medio-lateral episiotomy to avoid tearing**
Expert Review

- Informed Consent/Informed Refusal
- Was it standard of care to allow a first time mother with an epidural and positioning complications to push for five hours and still have an operative vaginal delivery
- Medical record did not describe discussion with the patient regarding her options related to a forceps versus C-section — the physician remembered having a 30 minute consent discussion
- Question: do the nurses witness these discussions and what type of team documentation can be done to help establish this?
- This can avoid the bringing of a case
- The case was dismissed, many depositions later — let’s avoid the bringing of a case!!
Team Approach to L & D Documentation?

Even a Little More Detail will Help Us Defend the Case
Real Time Documentation of Refusal will Help

- As part of the team **real time** detailed documentation of:
  - Progression of labor
  - Hand-offs
  - Labor stages
  - Moving toward C-section?
  - Instrumented delivery?
  - Witnessed discussions with patient
- Much better than after the fact, especially after a birth injury
• Example of Visitor/Patient behavior:

• “… every time I entered the room to check patient, the wife will go into toilet and won’t come out … wife stayed in bathroom for 1 hour … Security and house supervisor called … when supervisor opened bathroom door, the patient’s wife was found on the floor, holding syringes. Wife was escorted out of the room by Security … MD on call made aware … will monitor patient”
Cynthia was admitted from ED late in the evening. She has a complex medical history, is a high user of opioids but we have no notice that she mis-uses drugs; she denies such a history.

No warning in our EHR that she has behavioral issues from prior hospitalizations or clinic visits.

At 8 a.m., the nurse observes the patient slumped over with a syringe in her hand; her IV is cloudy.

A code ensues to no avail: It is a Coroner’s case.
What was in Cynthia’s bag?

- Oxycodone galore
- Pipes
- Butane lighter
- Charred foil
- Marijuana
- Other drug supplies
- Her estranged family told physician and coroner that she had a drug addiction, including heroin
- Should the case be reported to CDPH?
- What about liability?
What is the Duty?

• In an unpublished but favorable opinion, the Court of Appeal ruled that a voluntary drug treatment center had no liability to a resident who smuggled in and used heroin at three in the morning.

• They used “tied together” shoe strings to bring it in thru a window.

• Court ruled that no duty, not a health care facility.

  Hollywood v. Superior Court (2018) previously published at 21 Cal App 5th 70
What’s Coming into the Hospital? The Stakes are Much Higher Now

• Purpose of our policies:
  • Health and safety of patients, visitors and staff
  • Zero tolerance of drugs, alcohol or smoking
  • There are no designated smoking areas
  • Weapons — loaded guns, clubs, pipes, drug paraphernalia
  • Prescription drugs either not prescribed or that patients want to use on top of the meds we give them
    • We have responsibility for medication management
Issues with Belongings: Drugs and Contraband — Possible way to Manage

• Procedure if you observe or suspect usage/possession
  • Inform manager, Hospital Supervisor, Risk Management, Attending physician
  • RM, Security & Nursing Supervisor, in consultation with attending, will decide if patient’s room will be examined
  • Complete Incident Report
  • Make a note in medical record

• Examination of patient’s room
  • Patient advised of examination at the time of exam, **not before**
  • Done by two staff, one of whom is from Security
  • Security should document
Examination of Rooms/Belongings

• Policy: to balance the patient’s right to privacy with the safety and security of patients, staff, and visitors

• Policy: decision to examine room or belongings should be based on reasonable cause for a search and when it is the least invasive and most effective means available to meet the safety, security and medical needs of the patients and staff

• But there is no expectation of privacy in a hospital room

It’s All About Safety!
Why do we Have the Right to Examine a Patient’s Room?

- The risk of death or serious harm from the patient taking either a drug NOT prescribed by hospital or illicit drugs
- Smoking products: flammability of oxygen and other gases
- Sharing of drugs among patients
- Fairness to other patients who are engaged in smoking cessation programs
- The increased risk of criminal activity with the presence of illicit drugs
- To avoid the risk of Work Place violence
- Risk of patient self-harm
But What About Examination of Belongings?

- If the patient is non-responsive, you need to know why — examination is done because it is an emergency.

- Examination of patient’s **belongings** — non-emergency
  - Patient advised of examination
  - Done by two staff, one of whom is from Security
  - Security should document
  - If patient refuses, then belongings will be sequestered and patient will be allowed reasonable access in the presence of a staff person.

- If during property inventory, patient declines, sequester and sequester if there is a warning of prior issues.
What if we Had Notice of an Issue with Cynthia for Potential Violence/Drug Use and we Didn’t Examine the Room?

Please check in with the Nurse

Before entering the room
Arguments

• We are NOT law enforcement; therefore the 4th Amendment of the Constitution regulating search and seizures by Government does not apply
• All adults are dependent adults when in our hospital
• For the most part, hospitals are open to the public around the clock
• Every hospital restricts weapons, drugs of any kind — what do we do to make sure we are weapon free?
• We have to comply with the Workplace Violence Protection Act to create policies and procedures to avoid violence
Arguments: Joint Commission

• The Joint Commission has commented that hospitals were once considered “safe havens” but:
  
  • As criminal activity spills over from the streets onto the campuses and through the doors, hospitals face particular challenges in securing the building … these challenges are especially difficult in high-traffic areas which have high-stress levels such as the emergency departments

• EC.01.01.01 requires hospitals to have a written plan for managing the security of everyone who enters the hospital facilities.

• EC.02.01.01: Safety risks may arise from structure ... Safety incidents are most often accidental. On the other hand, security incidents are often intentional. Security protects individuals and property against harm or loss. Examples of security risks include workplace violence, theft, infant abduction, and unrestricted access to medications. Security incidents are caused by individuals from either outside or inside the hospital.
Balancing of Interests

• Did the patient retain any expectation of privacy in the belongings or area searched (argue they do not, especially in ED); and

• If such a privacy interest existed, whether it is diminished or subordinate to a legitimate interest, such as:
  • Obtaining information relevant to determining appropriate care
  • Protecting patient property while hospitalized
  • Prevention of claims related to property
  • Protect staff and other patients from potential dangers
Thank You

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