Informed Decision-Making and Labeling

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Informed Decision-Making

- Perspective on benefit versus tolerance for risk lies with the patient
- Communicated by the provider
  - Address patient goals, preferences, concerns
  - Discuss anticipated benefits and possible risks
  - Inform, not influence

Dermal Filler Labeling

- Labeling is a part of the informed decision-making process
- Components
  - Device Description
  - Indications for Use
  - Precautions and Contraindications
  - Benefits and Risks
  - Alternatives
  - Premarket and Postmarket findings
  - Other information to enable an informed decision

Communicating Risks

- Labeling is updated as further information becomes available
- Intended uses and anatomical locations continue to evolve
- Current practices may not adequately communicate risks to patients
- May require additional strategies to communicate labeling information

Consistency in Patient Labeling

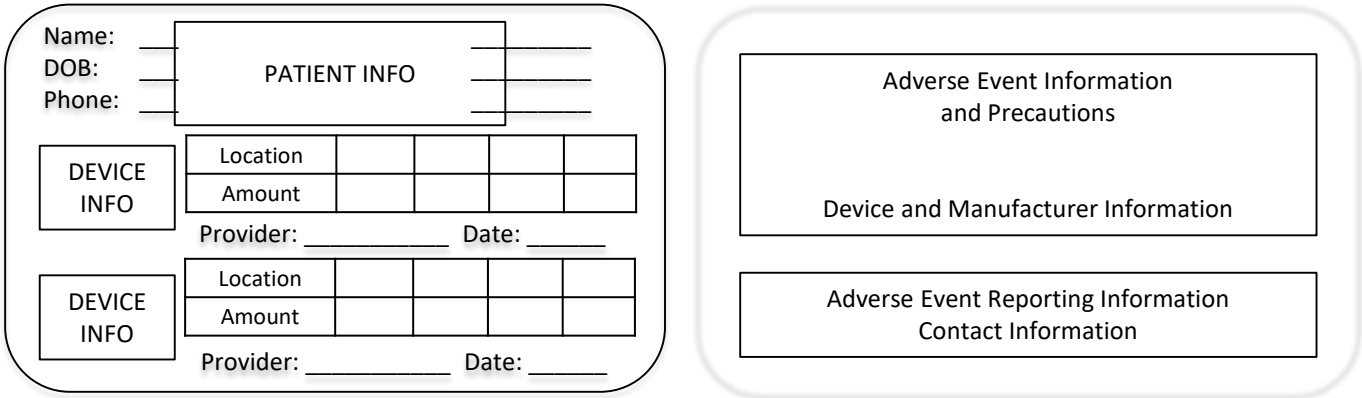
- Develop consistent labeling among Sponsors
  - Structure and content as discussed previously
  - Consistent presentation of benefits and risks
  - Inclusion of additional information for anatomical areas or intended uses with different risk profiles

Additional Examples of Strategies

- Boxed Warning
  - Regarding the risk of intravascular injection
- Patient and Provider Decision Checklist
  - Includes risks from labeling
  - Specific mention of risks of intravascular injection
  - May be required for areas of increased risk
  - Allows patients and providers to acknowledge understanding

Patient Device Card

- Injection information may not be readily available to patient
- A patient device card can provide injection information
- Can include post-procedure precautions and instructions
- Example:



Benefits of a Card

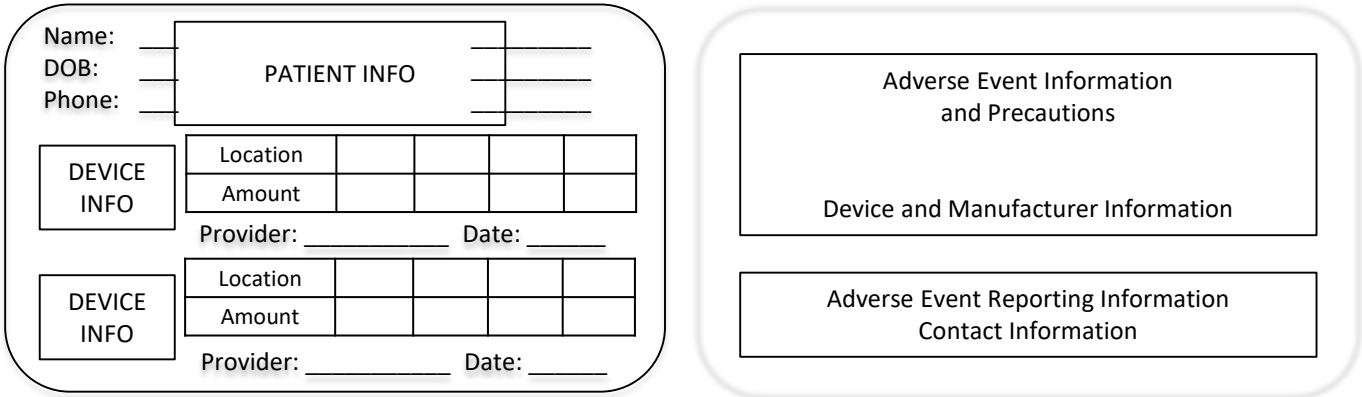
- Record of the injected device and its unique device identifier
- Information about common and serious adverse events
- Allow for continuity of care should patient transition care between providers
- Allow for patient to follow device updates, such as for safety or potential recall
- Instructions for medical device reporting and manufacturer contact information

Panel Questions

The Panel will be asked whether the current strategies are adequate, or if additional strategies are needed to appropriately convey risks to patients. The panel will be asked to comment on the example strategies.

Panel Questions

The panel will be asked for their recommendations on a patient device card as a part of patient labeling. The panel will be asked to comment on the proposed mock-up card example.

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