The Nocebo Effect and Informed Consent

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Nocebo Effect

- **Placebo Effect**: a beneficial effect produced not by a drug or treatment but by the a patient's belief that a drug or treatment will produce said beneficial effect
- **Nocebo Effect**: the mirror phenomenon to the Placebo effect, where the likelihood that a patient will experience negative side effects from a drug or treatment increases if the patient knows about the possible side effects
- In an essay discussing the nocebo effect, which was published in 2014, Shlomo Cohen states that a search for "nocebo" in the Philosopher's Index "yields a striking zero result."

Nocebo Effect Examples

- **Beta blockers**
  - Beta blockers are used to lower blood pressure, and it is widely known that beta blockers can cause impotence in males.
  - Clinical trial with three groups:
    - Group (A) Patients were not told the name of the medication or the side effect
      - *3.1% suffered the side effect*
    - Group (B) Patients were told the name of the medication but not the side effect
      - *15.6% suffered the side effect*
    - Group (C) Patients were told the name of the medicine and the side effect
      - *31.25% suffered the side effect*

Nocebo Effect Examples

- **Aspirin to treat angina**
  - Gastrointestinal problems are a possible side effect of aspirin
  - Clinical trial with two groups:
    - Group (A) patients were *not* informed of the possible side effect
    - Group (B) patients *were* informed of the possible side effect
  - Six times as many patients in group (B) withdrew from the study complaining of gastrointestinal symptoms

Nocebo Dilemma

- Duty to respect patient's autonomy (informed consent)
- Duty of nonmaleficence

- The dilemma: the physician can either act in accordance with the duty to respect a patient's autonomy and therefore not act in accordance with the duty of nonmaleficence, OR act in accordance with the duty of nonmaleficence and therefore not act in accordance with the duty to respect a patient's autonomy.

Patient Care: Paternalism to Autonomy (and Back?)

- 1972: Canterbury v. Spence
- 2003: Raanan Gillon, “I personally believe that emphasis on respect for autonomy is in many circumstances morally desirable and why I personally am inclined to see respect for autonomy as *primus inter pares* – first among equals – among the four principles.”
- 2014: Shlomo Cohen: “The list of the myriad irrationalities that people ordinarily exhibit in decision-making defies repetition, and this contradicts the presumption that the practice of obtaining informed consent, in its common universal form, rests on a duty to respect people’s autonomous choice.”
- 2014: Shlomo Cohen: “its ethical point is indeed more elementary than respect for autonomous choice: it is to provide reasonable assurance that a patient has not been deceived or coerced.”

Managing the Nocebo Effect

1. Subsume autonomy under nonmalificance, eliminate the dilemma.
   - **Response:** it is false to claim autonomy is grounded in nonmalificance. Autonomy is a value that stands on its own.

2. Shlomo Cohen: physicians ought to look at A) the likelihood that a medication will cause nocebogenic effects and B) whether a specific patient is likely to suffer nocebogenic effects. If there is a high likelihood that the medication will cause nocebo efects and a high likelihood that a patient is susceptible to nocebogenic effects, then we ought to consider withholding informed consent in order to act in accordance with the duty of nonmalificence
   - **Response** from Fortunato and colleagues: Cohen's approach was ethically sound, but impractical. It would be practically impossible to learn the nocebogenic potential of every medication.

Managing the Nocebo Effect

3. Fortunato and colleagues:
   - Patients that are particularly anxious or have previously experienced the placebo effect are more likely to suffer the nocebo effect, and these are the patients that physicians should consider withholding information from.
   - Informed consent should be handled *after* the initial treatment through a follow-up call. If the patient is experiencing known side effects, the physician would then inform them during the follow-up call that that those are indeed known side effects

Response to Fortunato and Colleagues

- **Impractical**: Ironically, Fortunato and colleagues' approach is also impractical. Given that we go to walk-in clinics, are often referred to specialists that don't know us, etc., it is unlikely that a physician can ascertain whether or not a patient is likely to suffer from nocebo effects.
- **Overly Paternalist**: Fortunato and colleagues do not instruct physicians to take into account how much value a patient puts on autonomy or informed consent.
- **Distrust of Physicians**: If patients learn that physicians will withhold information, patients will question whether physicians are telling the truth. This may lead to the patients investigating side effects at home, which is especially problematic because physicians will not be present to put the side effects into context or to reassure the patient.

A Better Approach

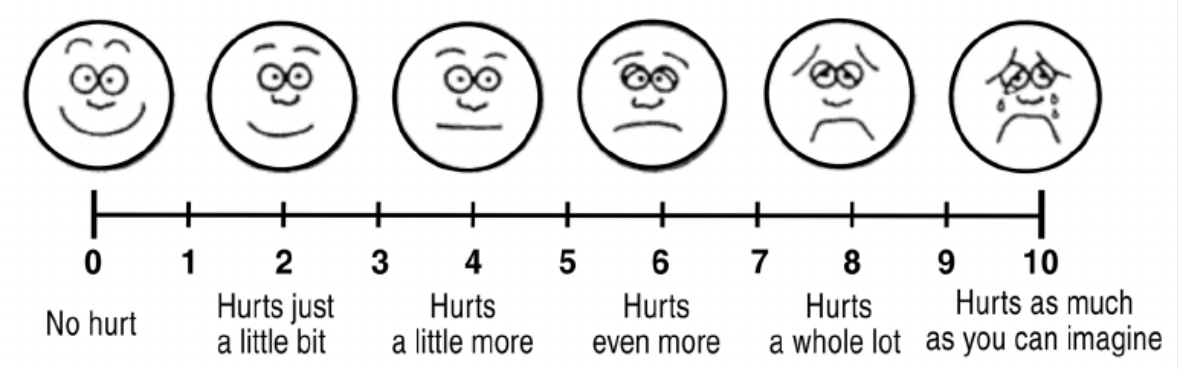
- Distinguish between two types of cases:
  1. *Cases where there is very little choice involved. I.e., there is only one possible treatment (or one superior treatment) or the patient has already decided on the treatment*
  2. *Cases where there are more than one viable options for treatment and the patient has not decided*

- Values in conflict: Non-maleficence, Autonomy (provide reasonable assurance that a patient has not been deceived or coerced), Physician Trust

- Category 1 cases: Non-maleficence justifies non-disclosure. Autonomy justifies non-disclosure. Physician Trust justifies non-disclosure. So the default should be to *not* disclose the side effects in these cases. This is practical, there is no coercion, and it does not erode trust in physicians.
- Category 2 cases: Non-maleficence justifies non-disclosure. Autonomy (more complicated) – patients may believe they were deceived or coerced if they weren't told about side-effects. Autonomy justifies disclosure. Physician trust justifies disclosure. The default should be disclosure. This respects autonomy and avoids creating a distrust in physicians.

A Tool for Overriding Defaults

- Like most defaults, the defaults for category 1 and category 2 cases can and sometimes should be overridden.
- The tool: a scale that measures attitudes towards autonomy, much like the universal pain assessment scale.



0 – I want to know everything
10 – unless the harm is great, I don't want to know anything

- Use this tool at the beginning of appointments
- Robust shared decision making

Concluding Remarks