

Consent and blood transfusion

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Speaker disclosures

- Clinician and researcher
- Member or chair of various ethics committees
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- Director of ethics centre
- Executive Director of Global Reconciliation
- Previous collaborative relationships in research projects with pharmaceutical companies

What is consent?

- An ethical and legal concept
- Generally refers to verification of agreement between the parties in a medical treatment or intervention
- In Western societies often linked to concepts of individual “freedom” and “identity”
- Various attempts have been made to codify the process of consent

What is consent?

- The outcome of a complex process of dialogue within a relationship with a defined ethical structure in which the parties agree on a particular course of action.

Part 1

The formal structure of consent

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Some components of consent

- Competence or the ability to decide
- Voluntariness or free choice
- Disclosure of relevant information
- Understanding of facts and arguments
- A decision making process
- Authorization by the patient to proceed

Components of consent

- “Competence” or the “ability to decide”
- “Voluntariness” or “free choice”
- “Disclosure” of “relevant information”
- “Understanding” of “facts” and “arguments”
- A “decision making process”
- “Authorization” by the patient to proceed

- What are the philosophical sources of this account of consent?
- What are the benefits of an operational definition of the criteria of valid consent?

Exceptions to the assumption that consent for medical treatments is needed

- Emergency settings
- Lack of competence:
 - Minors
 - Critical illness
 - Psychiatric illness
 - Dementia
- Research

What information should be provided?

- Objectives, reasons and evidence
- Risks and benefits
- Details of the procedures
- Alternatives to transfusion
- Consequences of different courses of action
- What might be done in response to different outcomes
- Relevant dualities and conflicts of interests etc.

What risks should be disclosed?

- Common risks of little consequence
- Rare but serious hazards
- Risks for specific patients
- “Unknown risks”

Unknown risks

- Risk of unidentified viruses
- Risk of transmission of prion diseases
- Other possible risks: immune reactions, ARDS etc.
- How is it possible to disclose risks of unknown dangers? How valid is any decision to accept those risks?

The case of Jehovah's Witnesses

In general, there is broad (but not unanimous) agreement that:

- The views of competent individuals regarding religious beliefs should be respected; and
- In the case of children the views of the broader society should usually prevail.

The case of Jehovah's Witnesses

Of particular interest are:

- The continuing discomfort among health professionals about withholding transfusions
- Improvements in practice that have emerged in relation to attempts to avoid transfusion.

Part 2

Consent as a dynamic process

Special issues in the consent process

- The fluidity and complexity of the clinical relationship
- The creative and dynamic nature of the ethical bond
- The constitutive role of communication

Special issues in the consent process

- The creative and dynamic nature of the ethical bond

Special issues in the consent process

- The constitutive role of communication

Consent involves at least two components:

- Identification of the information to be conveyed
- Communication with the patient

Communication is a dynamic process that cannot be fully codified

- It is not merely concerned with the transmission of information
- It is often a process of mutual exploration and discovery
- It involves dialogue across different frameworks of knowledge, value systems and cultures
- The signing of a form is no more than an indication that a discussion has taken place...

Communication is context-sensitive and culturally dependent

- The significance of time, place and person may all be of importance
- The context of chronic disease may be different from that of acute illness
- Special cultural meanings may be evoked in relation to the substance and process of the discussion
- Communication is therefore neither a formal technical “skill” nor a collection of spontaneously improvised verbal responses

Some conclusions

- Consent can be characterized within different conceptual frameworks
- The description of formal components or criteria can be helpful both as an analytical tool and to provide practical guidance

Some conclusions

- The dynamic complexity of the ethical context is irreducible
- The process of clinical communication includes both provision of information and exploration and discovery
- The heterogeneity of theoretical frameworks, value systems and cultures adds a further dimension of complexity.

The many variables active within the consent process

- Philosophical ideas of freedom and personal autonomy
- Concepts of personality and identity
- Ideas of knowledge, truth, uncertainty, risk
- Different value systems and cultural frameworks
- The structures and assumptions underlying the clinical relationship
- Relationships within and between families and communities
- Legal and administrative frameworks of regulation and authority

- Trust and responsibility
- Vulnerability and the offer of care
- Fear, uncertainty, physical and mental pain
- Gratitude, altruism, resentment

- Multiple and changing discourses
- Changing medical, personal and social circumstances

Summary and conclusion

- The three Isbister machines representing:
 - knowledge
 - personal experience and
 - clinical judgment

THE INTERVENTION

SCIENCE BASED MEDICINE

Should it work?

Pathology/Pathophysiology

"The facts"



CLINICIAN BASED MEDICINE

Will it work for MY patient

Clinical decision making

Opinion, Experience, Context

"The individual patient"

N=1

EVIDENCE BASED MEDICINE

Does it work?

Epidemiology

Numerical Analysis

"The average patient"

N=X



DECISION



PATIENT BASED MEDICINE

Patient advocacy

Informed consent



THE OUTCOME

THE INTERVENTION

SCIENCE BASED MEDICINE

Should it work?



Technology/Pathophysiology
"The facts"

CLINICIAN BASED MEDICINE

EVIDENCE BASED MEDICINE

Does it work?

Epidemiology

Numerical

"The average"

OUTCOME BASED MEDICINE

What endpoints were used?

Surrogate

Real

Patient
Clinical
Context
"ent"

Did the intervention work in the short/long-term?

Were there any adverse events?

?error (system versus individual)

?accepted risk balanced against anticipated benefit



Benefit



PATIENT BASED MEDICINE

Patient advocacy
Informed consent



THE OUTCOME

There is no evidence

Could
mean

Could
mean

Nobody has looked

Assumed knowledge, logic,
Common sense, dogma,
GOBSAT

Somebody has
looked

No evidence of benefit or
risks outweigh benefit/s

On what basis do I make decisions?

How should I treat my patient now?

There is no evidence

Could mean

Could mean

Nobody has looked

Somebody has looked

Assumed knowledge
Common sense, c

ce of benefit or
weigh benefit/s
sions?

GOBSAT
On what

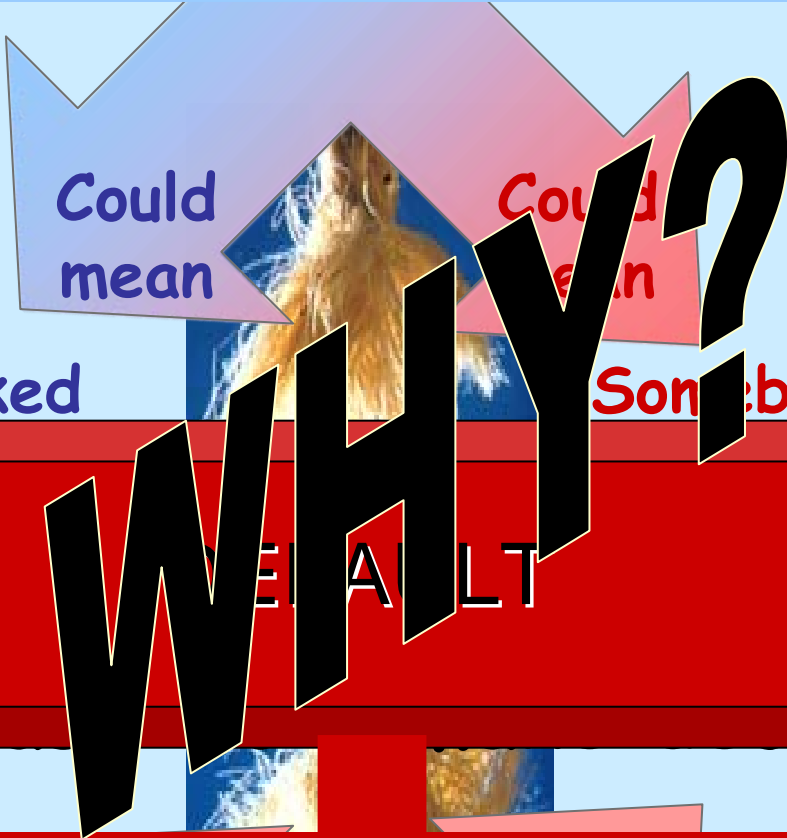
DEFAULT

Do I give a blood transfusion?

How should I treat my patient now?

GIVE

There is no evidence



Could mean

Could mean

Nobody has looked

Somebody has looked

Assumed knowledge
Common sense, d
GOBSAT

ence of benefit or
weigh benefit/s

On what

sions?

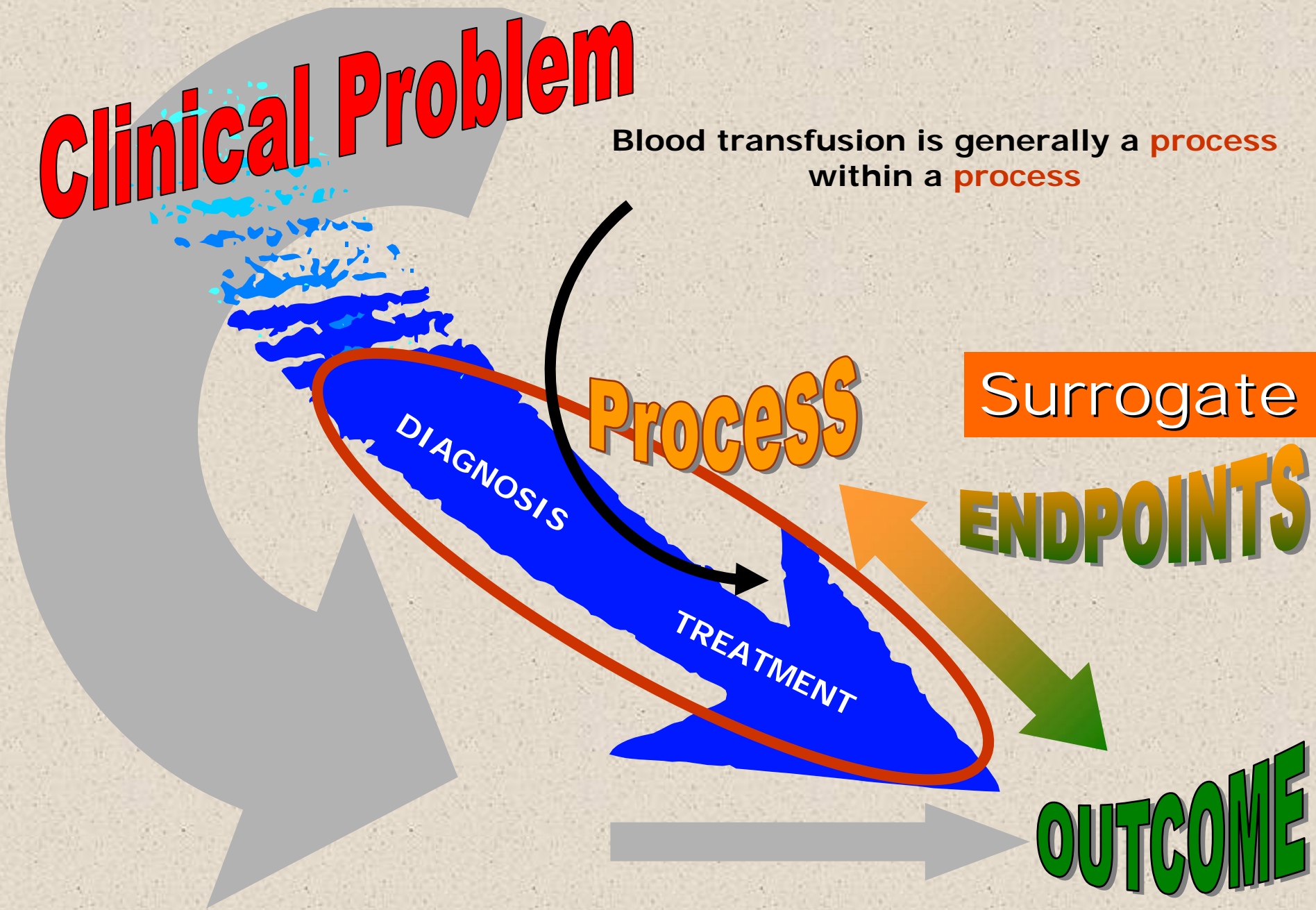
Do I give a blood transfusion?

How should I treat my patient now?
GIVE TRANSFUSION

PATIENT

Clinical Problem

Blood transfusion is generally a **process** within a **process**



Surrogate

ENDPOINTS

OUTCOME

Process

DIAGNOSIS

TREATMENT

