

UNIT-III

COMMUNICATION IN PHARMACOVIGILANCE



CENTURION
UNIVERSITY
*Shaping Lives...
Empowering Communities!*

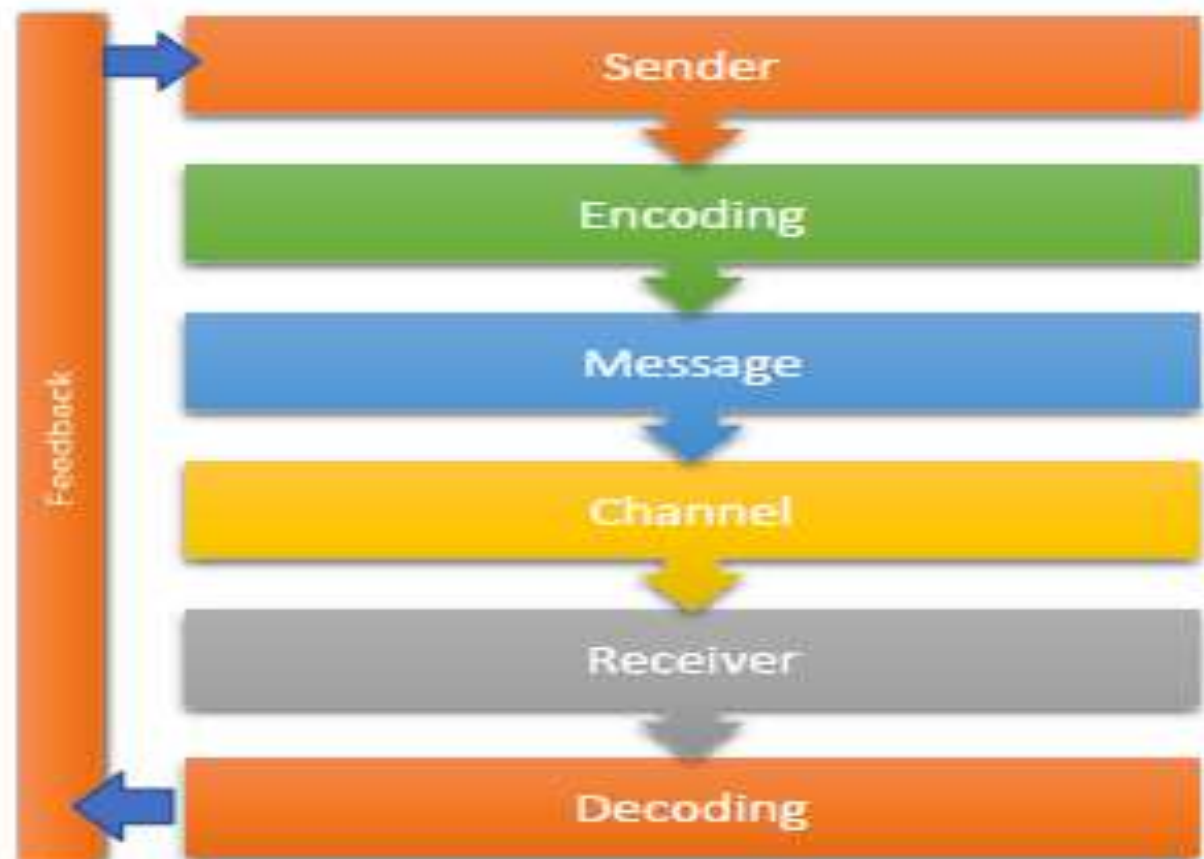
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- **Effective communication in Pharmacovigilance**
 - **Communication in Drug Safety Crisis
management**
 - **Communicating with Regulatory Agencies,
Business Partners, Healthcare facilities &
Media**

Communication:

The act of sharing or exchanging information, ideas or feelings.

Communication Process:



Principles of Good Pharmacovigilance Communication

- ✓ Relate the messages to the audience's perspective
- ✓ Avoid comparisons which trivialize the concern
- ✓ Ensure completeness of the message
- ✓ Be balanced, honest and sympathetic
- ✓ Focus on the specific issue that needs to be handled
- ✓ Pay attention to what the audience already knows
- ✓ Be respectful of people's right to be concerned
- ✓ Be honest about the limits to scientific knowledge
- ✓ Acknowledge uncertainty
- ✓ Evaluate the impact of your message

✦ Effective Communication in Pharmacovigilance

One can achieve effective way of communication just by following the principles of good pharmacovigilance communication.

✦ Why do we need to improve our communication?

- ✓ Improve patient care and understanding
- ✓ Eradicate disease / improve disease control
- ✓ Promote transparency and accountability

✦ Why do Communications matter in Drug Safety?

- ✓ For Welfare of millions of people worldwide
- ✓ To overcome Extreme dangers of failure
- ✓ Communications are commonly poorly executed, second-rate and ineffective, so to improve the quality.

+ Communication Challenges:

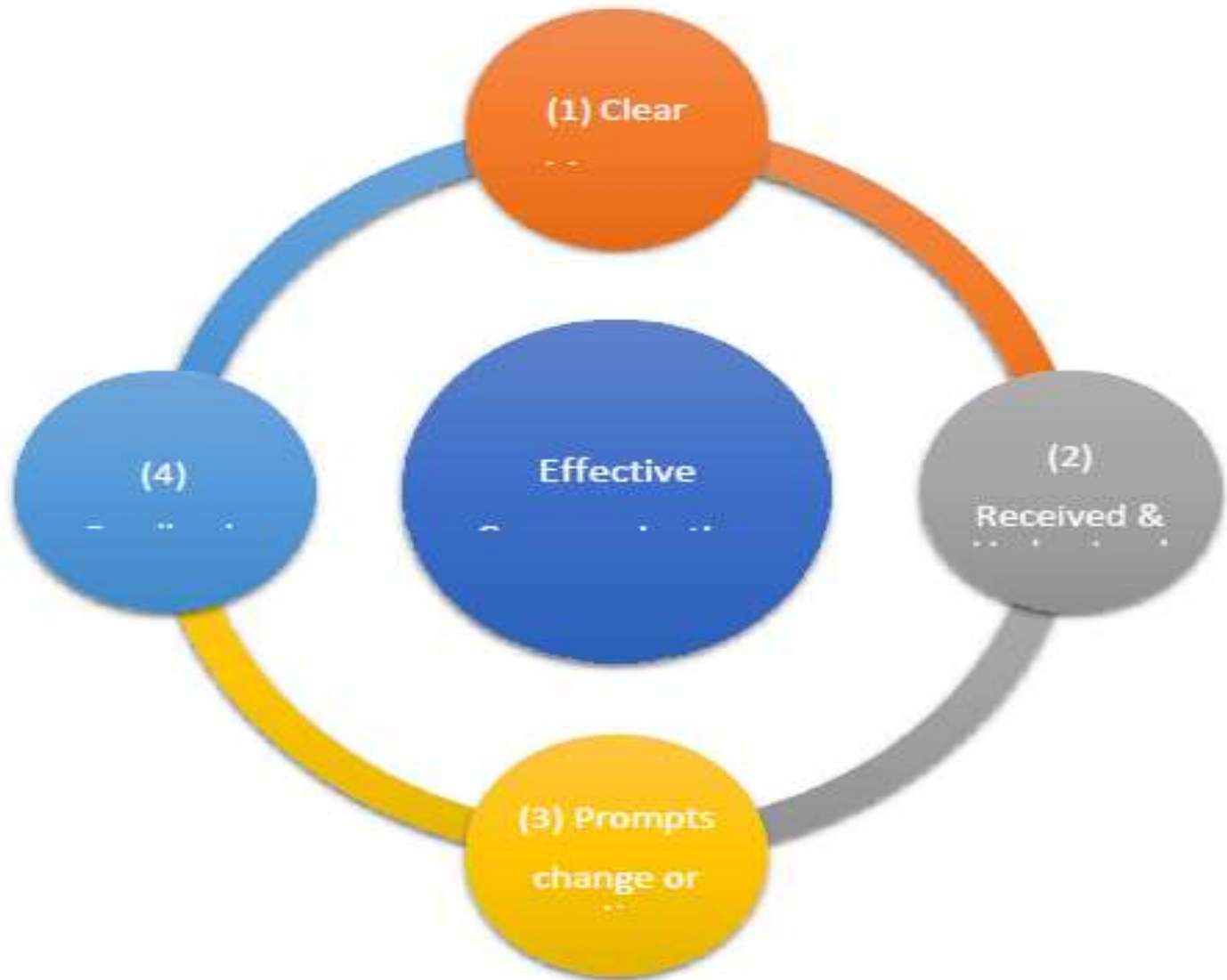
- ✓ The importance of ADRs and reporting them
- ✓ Information about benefit – harm and effectiveness – risk
- ✓ Encouraging rational drug use/adherence
- ✓ Communicating uncertainty
- ✓ Dealing with traditional beliefs and practices
- ✓ Involving patients; reaching informed consent
- ✓ Preventing or resolving crises

+ Problematic issue in Drug Safety:

all reliant on communications for safety

- ✓ Adverse effects: 'no drug 100% safe'
- ✓ Risk as a concept in medicine
- ✓ Safety and medicines (prescribing, dispensing)
- ✓ Benefit-harm
- ✓ Effectiveness-risk
- ✓ Public health and commercial goals
- ✓ Public health and individual welfare
- ✓ Access to medicines
- ✓ Uncertainty

What is an Effective Communication?



Principles of Effective Communications

- ✓ Be clear about your message and purpose
- ✓ Know your audience(s): empathy; tailor the message
- ✓ Choose appropriate methods/media
- ✓ Present message with impact
- ✓ Make benefits clear
- ✓ Pre-test and revise message
- ✓ Repeat message
- ✓ Seek feedback, monitor effects, start again

Qualities of Modern Communications:

- ✓ Intimacy
- ✓ Immediacy and high impact
- ✓ Peer-to-peer
- ✓ Addressing competition and low attention levels
- ✓ Benefits

Planning Communications:

- ✓ Today's modern standards and methods
- ✓ Simple, clear message
- ✓ Stimulating motivation and offering benefits (including rewards and feedback)
- ✓ The use of specialist skills and creative imagination

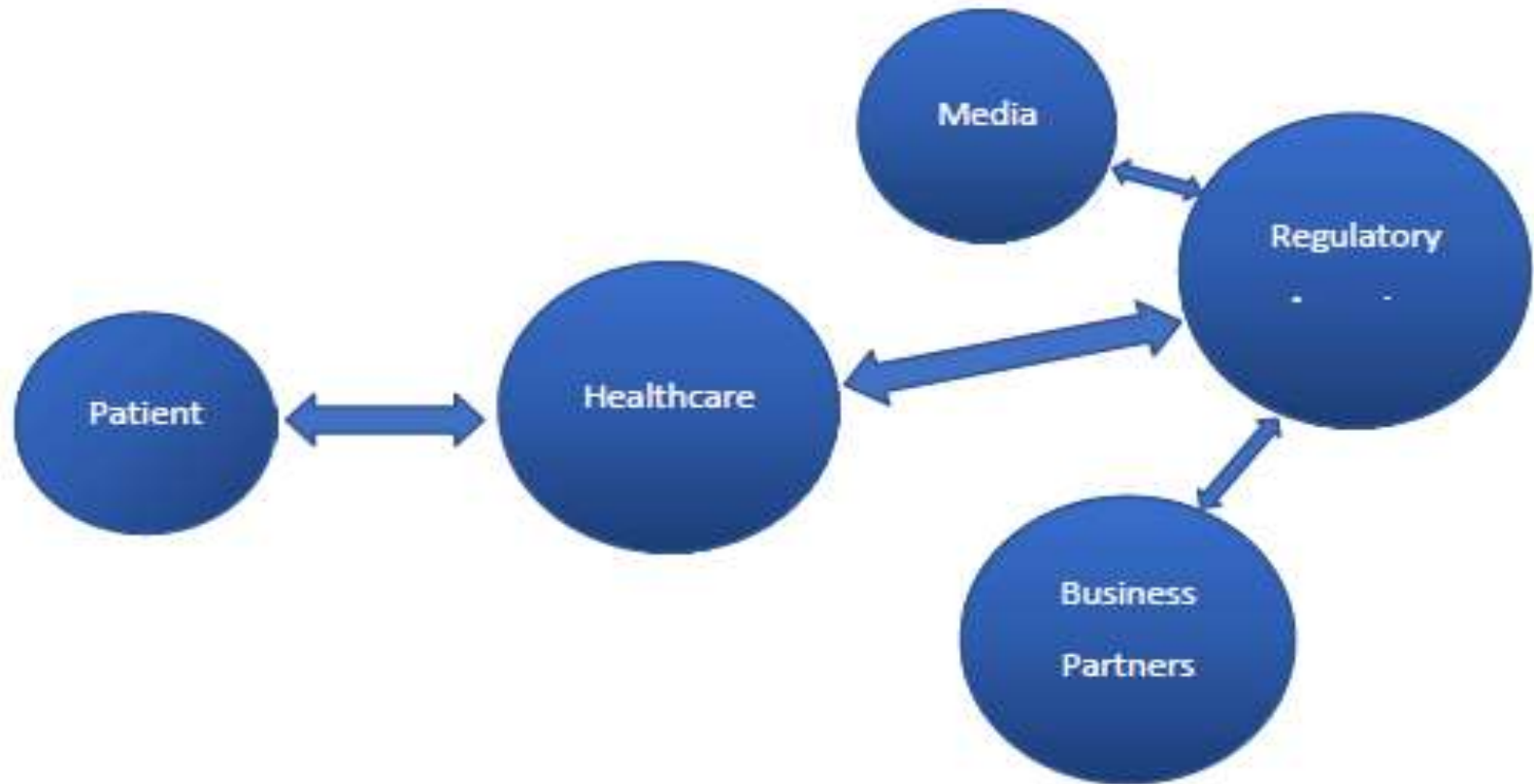
Summary:

- Our communications must:
 - Be strong and visible
 - Be precisely targeted and tested
 - Change attitudes, values, behaviour
 - Be followed up and revised
 - Embrace modern standards and skills

1. Communication in Drug Safety Crisis Management

- Crisis will happen (fire, death, ADRs...)
- Assess risks
- Anticipate and plan for all likely and unlikely events
- Create, rehearse and revise crisis plans
- In crisis, communicate
 - Quickly
 - Openly and honestly
 - Express regret, apologise
 - Explain what is being done to solve the crisis and prevent repetition

2. Communicating with Regulatory Agencies, Business partners, Healthcare facilities & Media



Communication with Media:

✦ Who are the media?

- ✓ Print -magazines, newspapers, community newspapers
- ✓ Electronic -radio, TV, internet
- ✓ Local and national levels

□ **Some basic questions a reporter will ask you....**

- ✓ WHO-is affected, responsible
- ✓ WHAT-has happened and what is being done about it
- ✓ WHERE-has it happened
- ✓ WHEN-did it happen
- ✓ WHY-did it happen
- ✓ WILL-it happen again

□ **Communications practices to avoid**

- ✓ “Spinning”! (distortion or decoration of facts for beneficial effects)
- ✓ All communications are subjective, but do not be manipulative or dishonest
- ✓ Avoid “No comment”—rather say why there’s nothing to say and what is being done
- ✓ Avoid confusing statistics
- ✓ Do not avoid taking responsibility
- ✓ Don’t attack the messenger/accuser
- ✓ Don’t deny, justify or excuse your mistakes

□ Partners & Audiences in Drug Safety:

Partners

- Manufacturers
- Regulators
- Politicians
- Employees
- Health professionals
- Academics
- Bosses/managers

Audiences

- The public
- Patients
- Consumer groups
- Lawyers
- The media
- International community