The role of the patient in pharmacovigilance
TGA perspective

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Overview

- Importance of involving patients in pharmacovigilance
- TGA’s current approach
- Challenges for involving patients in pharmacovigilance
- Opportunities for involving patients in pharmacovigilance
- Future TGA initiatives
Importance of involving patients in pharmacovigilance

- TGA’s role is to safeguard and enhance the health of the Australian community through effective and timely regulation of therapeutic goods: direct line of sight to consumers and their experiences is vital in enabling us to do this
- Patient empowerment
- Consumers often much better able to articulate non-clinical aspects of their adverse events
- Consumers may report different ADRs than healthcare professionals (HCPs)
- Involving consumers can overcome some barriers that may prevent HCPs from reporting
- Builds trust in the Australian regulatory system and health system
- Identification of product quality issues and tampering
Source of TGA ADR reports 2016

- Sponsor: 54%
- State/Territory Health Department: 17%
- Hospital pharmacist: 11%
- Community pharmacist: 5%
- Consumer: 6%
- Medical specialist: 4%
- General practitioner: 2%
- Nurse: 1%
- Coroner's court: 0%
- Complementary healthcare practitioner: 0%
- Dentist: 0%
Source of TGA reports 2012-2016

- Sponsors
- State and Territory Health Departments
- Hospitals and hospital pharmacists
- Community pharmacists
- General Practitioners
- Consumers
- Other

The role of the patient in pharmacovigilance
The Consumer knowLEdge adVerse Event Reporting (CLEVER) project

• TGA identified a decrease in reports from consumers from 2011 – 2014
• CLEVER project initiated in collaboration with ARCS, Consumer Health Forum of Australia, NPS MedicineWise, University of Sydney
• Qualitative study using focus groups to explore consumers’ opinions about adverse events associated with medicines, vaccines and medical devices, and experiences with managing and reporting adverse events

• Major findings:
  - The term ‘side effect’ was most commonly known amongst consumers with relatively few recognising the terms ‘adverse event’ or ‘adverse reaction’
  - Most people did not expect to experience a side-effect
  - Participants were generally unaware of AE reporting avenues and of the TGA and its regulatory activities
“out of the ordinary”

“allergic reaction”

“an overreaction”

“unwanted”

“negative”

“unintentional”
The **Consumer knowledge adverse event reporting (CLEVER)** project

- Major findings continued:
  - Participants saw value in reporting for themselves and the greater medicine-taking population to improve safety, monitoring and quality of medicines
  - Predominant opinion from consumer participants was that side effects should be reported to the doctor, or as some suggested the pharmacist, who would then report the information
  - Reporting had to be easy, accessible and time-efficient
  - Consumers would like feedback on their reports
  - There was no consumer insight that a sponsor could access AE information or even if they would want the information
The Consumer knowLEdge adVerse Event Reporting (CLEVER) project

• “I would like to report it but I’m so busy running around and I’m so forgetful that I would either a) forget it if it wasn’t easy and quick for me to do it or b) just not have time to go somewhere to actually report it. If it was easy to report I would definitely do it.”

• “I think if you’ve got to go jump through hoops and everything, answer a whole, 30 page document, and you just go, “Nup. Couldn’t be bothered.”

• “I prefer to report to the government because I feel like it would be taken more seriously rather than a call centre, a representative working for a company.”
TGA’s current approach

- Website content developed specifically for consumers – link for reporting problems is prominent
- Multiple ways consumers can report, including online form designed for consumers to “report a side-effect”
- Consumers receive an acknowledgement letter with their ADR number
- FAQs about adverse event reporting for consumers
- Transparent safety information: PI and CMI on website, DAEN, safety alerts
- Consumer representatives on committees
- TGA Twitter feed @TGAgovau
Involvement of patients in RMP activities

• Consumer activities may be included as part of the Risk Management Plan for new medicines, especially for the post-marketing period, e.g.:
  – Post-authorisation safety studies or registries where patients play a role in collecting ‘real world’ data
  – Patient alert cards
  – Patient education apps, websites and printed materials
• It is anticipated that such activities may increase with the introduction of provisional approvals.
Challenges

• Variation in health literacy
• Meeting consumer expectations
• Translating assessment of benefit-risk at the population to an individual consumer’s experience
• Regulatory issues vs clinical practice issues
• Vexatious complaints
• Incomplete information in AE reports
• Media interest and stimulated reporting
• New technologies and social media
• Mistrust of Government and Industry

"You can't list your iPhone as your primary-care physician."
Opportunities

• Better engagement with health literate consumers and better education of consumers with lower levels of health literacy
• Better engagement with patient and consumer groups
• Better engagement of consumers via new technologies and social media
• Better collaboration with Industry to encourage patient involvement in pharmacovigilance
• Better engagement with mainstream media to create positive news stories
• International collaboration and adoption of successful strategies implemented internationally
New/future TGA initiatives

• Medsearch app (and future upgrades)
• Black triangle launching in 2018
• PI reformat
• Revamp of consumer content on website
• Looking at whether can link CMI and ADR reporting to My Health records
• Participation in international project with other regulators, aimed at increasing consumer adverse event reporting