IPPOSI
DISCUSSION PAPER

Reporting of Medicines Side Effects

Date of Discussion: June 22nd, 2017

Location: Patient and Public Involvement Summer School, University of Limerick, Ireland

Currently, many patients are unaware of how to report the side effects of medicines, and the information on how to report the side effects is found on off-putting leaflets. These leaflets often have symbols like inverted triangles, small text, and confusing jargon that make them less comprehensible to the patient. In addition, information leaflets are currently not provided to patients who receive their medicines in a blister pack. These patients are at high risk and are vulnerable because they require more assistance with complying with drug regimens and therefore should not be excluded from receiving information on side effects.

Although the leaflets are legally required to include certain information, it was agreed that there needs to be a better balance between these requirements and the accessibility of information for consumers − the patients. One recommendation suggested a specific layout and standardised text template for all leaflets. As leaflet information needs to be widely comprehensible, including by vulnerable populations like young people and persons with disabilities, it is necessary for the language on the leaflet to be reading age appropriate. It was recommended that NALA be involved in determining readability. There also needs to be a shift from solely using traditional ways of communication − instead of only utilising leaflets, there could be interactive alternatives like audio leaflets and apps, like the UK's Yellow Card and WebRadar apps, that allow patients to research medicines and report side effects. Similarly, pictures and symbols, like traffic lights that indicate risk levels, could be used along with text.

In addition to these practical suggestions, on a larger scale there needs to be improvements in the identification and transparency of roles. Each stakeholder, including the general practitioner, pharmacist, regulator, and patient has a defined role in the dissemination of medicine, including the reporting of side effects. Various roles and responsibilities, as well as reporting channels, should be communicated through a national public awareness campaign. This will allow patients to be informed about why and how they should report side effects as well as allow them to take responsibility for taking and monitoring their medicines. It was

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suggested that this increased accountability can contribute to increased patient adherence. Finally, a system should be organised that allows patients to know what happens after they report a side effect − this communication might also take place via an app.

Conclusion:

Altogether, in medicines research and development process there are a wealth of suggestions that can improve the patient involvement and enhance knowledge of the process, and many recommendations revolve around the ideas of improved communication and transparency. With regards to communication, allocating time for ongoing, equal, and two-way communication at all parts of process would be ideal and effective in increasing patient involvement as they share their lived experiences. Transparency and a clear definition of roles will also increase patient confidence, as well as patient responsibility for medicines adherence, monitoring and reporting. With more patient involvement in the various steps of medicines research and development, the gap is closed between patients and other stakeholders as strong partnerships form and compliance increases.



Useful resources:

- All outputs from the 2017 workshops are available at the link below: http://www.ipposi.ie/patient-experts-action
- The Irish Platform for Patient Organisations, Science and Industry (IPPOSI) http://ipposi.ie/
- The European Patients' Academy on Therapeutic Innovation (EUPATI) https://eupati.eu

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