





## VISION ACADEMY VIEWPOINT

The Vision Academy is a partnership between Bayer and ophthalmic specialists, established with the aim of addressing key clinical challenges in the field of retinal diseases: www.visionacademy.org.

# Real-World Evidence in Ophthalmic Clinical Practice: Conducting an Audit

## **Background**

Real-world evidence (RWE) provides understanding of patient experiences of disease and treatment beyond the randomized controlled trial setting. In ophthalmology, RWE can help to improve knowledge on the impact of visual impairment and its treatment, aiding the optimization and customization of treatment for each patient.

In clinical practice. anti-vascular endothelial growth factor treatment regimens often differ from the strict used in randomized controlled trials. 1,2 This makes access to RWE particularly important when assessing clinical outcomes in realworld practice. An audit provides the opportunity for clinical care teams to understand their own practice and their patients' clinical outcomes and to address any identified weaknesses. The real-world data collected during an audit also allow the experience of individual clinics to be benchmarked against data from the wider community.

Developed by the Real-World Evidence Steering Committee in February 2020

## **Viewpoint**

- Ophthalmologists should generate their own RWE by contributing to a larger data source such as a patient registry, or by conducting studies and clinical audits within their own practice or at a local or regional level
- The team conducting an audit should include representatives from all staff involved in the service
- The audit can be conducted using data derived from an electronic medical record platform, such as the Fight Retinal Blindness! (FRB!) project,3 Medisoft,4 or the Intelligent Research in Sight (IRIS®) Registry.5 These platforms allow for information on treatment and clinical outcomes for thousands of patients to be made available, thereby simplifying the audit-conducting process. Alternatively, where such platforms are not available, an audit of reliably captured clinical data can be conducted using patient charts or electronic medical records
- A number of types of clinical audit exist:
  - Standard-based assess whether relevant standards are being met or improvements are needed
  - Adverse/critical incident monitoring or screening adverse events
  - Peer review sharing learnings in the clinic to optimize quality of care
  - Patient surveys assess patient perspectives on the quality of service
- Audits can be prospective or retrospective, with each type having advantages and disadvantages

	Prospective audit	Retrospective audit
Advantages	Allows tailored data collection	Data collection not affected by knowledge that audit is being conducted
	More reliable data collection	Representative of day-to-day practice
Disadvantages	More time-consuming	Only data that are routinely and reliably collected can be used
	Practice could be affected if staff are aware they are being observed	Data completeness can vary

A clinical audit can be a systematic cycle that involves measuring clinical care against specific standards, with the aim of improving the understanding and quality of care and continuously monitoring it to sustain improvements

#### References

- 1. Garrison LP, Jr., Neumann PJ, Erickson P et al. Using realworld data for coverage and payment decisions: the ISPOR Real-World Data Task Force report. Value Health 2007; 10 (5): 326-335.
- 2. Talks J, Daien V, Finger RP et al. Utility of real-world evidence for evaluating anti-vascular endothelial growth factor treatment of neovascular age-related macular degeneration. Surv Ophthalmol 2019; 64 (5): 707-719.
- 3. Save Sight Registries. About us. Available at: https:// savesightregistries.org/about/. Accessed January 2020.
- Medisoft. Medisoft Ophthalmology. Available at: http://www. medisoft.co.uk/medisoft-ophthalmology. Accessed January
- Centers for Disease Control and Prevention. IRIS® registry at a glance. Available at: https://www.cdc.gov/visionhealth/vehss/ data/ehr-registries/iris.html. Accessed January 2020.

# Important points to consider when designing a clinical audit cycle

What visual measures will be assessed?

- What vision chart will be used for assessment?
- · Will the number of patient clinic visits and number of injections per year be measured?
- The measurement and data collection process can be tested during development (pre-pilot), just before data collection (pilot), and during data collection (monitoring)

#### Data measurement

- · How many centers will be included as data sources?
- Will electronic records and/or additional data entry be used?
- · How will you deal with missing data?
- The protocol for the clinical audit should instruct the person retrieving cases for inclusion in the clinical audit about how to handle the following:
  - Missing cases from the list of cases intended for inclusion in a clinical audit
  - Cases that are needed for a clinical audit but cannot be made available for data abstraction in the time available
  - Cases in the list intended for the clinical audit that do not meet the inclusion description
  - If the needed number of cases cannot be achieved

Data

collection

- Sample size and collection are important to ensure there is no bias in the selection of cases for inclusion in the audit
- · Representative samples ensure that the sample contains cases that represent the study population, e.g. every fifth patient
- Non-representative samples do not ensure that samples contain cases that represent the population, e.g. the first 10 patients who were receiving a new treatment regimen

#### **Patient** selection

# **Further considerations:** overcoming barriers to conducting multidisciplinary audits

- Sufficient time needs to be allowed for staff to contribute to data collection and interpretation
- Communication gaps between audit support staff and professional medical staff may arise due to confusion around staff roles within the team, a lack of clearly defined group tasks, and differences in professional backgrounds and priorities. Providing training to improve the technical capabilities of staff is key and requires careful planning