



### Learning Objective

Write, present, publish, and evaluate case reports following the CARE guidelines



### CAse REport Guidelines

From 2011–2013, a group of experts: clinicians, researchers, and journal editors developed **CARE** — reporting guidelines for CAse REports.





### Value in Healthcare

# Return on Investment (ROI) In Healthcare

Outcomes divided by Cost



#### 2013 CARE Presentation and Publications



















#### The EQUATOR Network



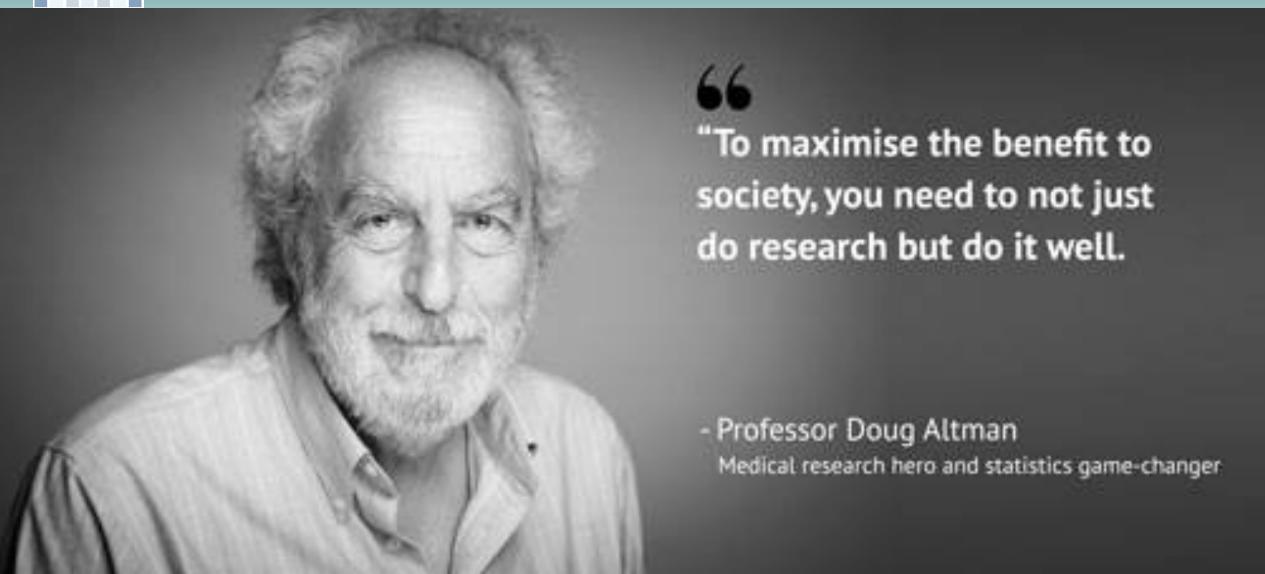
#### Enhancing the QUAlity and Transparency Of health Research

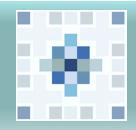
An international initiative providing a centralized resource for health research reporting guidelines.

Simera I, Moher D, Hirst A, Hoey J, Schulz KF, Altman DG. Transparent and accurate reporting increases reliability, utility, and impact of your research: reporting guidelines and the EQUATOR Network. BMC Med. 2010;8(24):1-6. doi:10.1186/1741-7015-8-24.



#### The EQUATOR Network





#### **CARE** Guidelines

A **Case Report** is a narrative that tells a story and includes data: presenting concerns, clinical findings, diagnoses, interventions, outcomes, and follow-up. The narrative should include a scientific discussion of the rationale for any conclusions and other 'take-away' messages.

Section	Item Number	Description
Title	1	The words 'case report' should appear in the title along with phenomenon of greatest interest (symptom, diagnosis, test, intervention, etc.)
Keywords	2	The key elements of the case in 2-5 words
Abstract	3	<ul><li>a) Introduction—What does this case add?</li><li>b) Case Presentation: symptoms, clinical findings, diagnoses, interventions, and outcomes</li><li>c) Conclusion and 'take-away' lessons</li></ul>
Introduction	4	Brief background summary referencing the relevant medical literature
Timeline	5	Depicts important milestones in this case as a table or figure
Patient Information	6	<ul> <li>a) Demographic information</li> <li>b) Main symptoms as described by the patient (chief complaint)</li> <li>c) Medical, and family history including lifestyle and genetic information when possible</li> <li>d) Co-morbidities, past interventions and outcomes</li> </ul>
Clinical Findings	7	Relevant physical examination findings

Scientific Writing in Health and Medicine



### **CARE** Guidelines

Section	Item Number	Description
Diagnostic Assessments	8	<ul><li>a) Diagnostic methods, challenges, and reasoning (including other possible diagnoses)</li><li>b) Prognosis where applicable</li></ul>
Therapeutic Interventions	9	Interventions (pharmacologic, surgical, clinician intervention, preventive, self-care, etc.) a) Administration of intervention (dosage, frequency, duration, etc.) b) Changes in the intervention (with explanations)
Follow-up and Outcomes	10	Summarize the clinical course of all follow-up visits including  a) Clinician assessed outcomes (patient assessment when appropriate)  b) Important follow-up test results (positive or negative)  c) Interventional adherence and tolerability (how was this assessed)  d) Adverse and unanticipated events
Discussion	11	<ul> <li>a) Strengths and limitations of the management of this case</li> <li>b) Relevant medical literature</li> <li>c) Rationale for conclusions (assessment of cause and effect)</li> <li>d) Conclusion — the main 'take-away' lessons from this case report</li> </ul>
Patient Perspective	12	The patient should share his or her perspective or experience when appropriate
Informed Consent	13	Did the patient give informed consent? Please provide if requested

Scientific Writing in Health and Medicine



### **EVIDENCE WE TRUST**



The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. - David Sackett (BMJ 1996) -



#### Overview

- ✓ History of Case Reports
  - ✓ Health Research Reporting Guidelines
    - Opportunities and Challenges



#### Case Report Opportunities

Good case reporting demands a clear focus, to make explicit to the audience why an observation is important in the context of existing knowledge. ??

Vandenbroucke JP. In defense of case reports and case series. Annals of Internal Medicine 2001;134(4):330-334.



### The Case for CASE REPORTS

Case reports and case series have a high sensitivity for detecting novelty and are a cornerstone of medical progress, providing new ideas in medicine. ??

Vandenbroucke JP. In defense of case reports and case series. *Annals of Internal Medicine* 2001;134(4):330-334.



### Uses for Case Reports

- New or rare diseases
  - Cost and Effectiveness
    - Adverse events
      - Education



### Case Reports

### Case Reports provide early signals:

- Of what works,
  - For which patients, and
    - Under which circumstances



### Case Report Examples

#### A case report could describe a pathology caused by the Zika virus



an organ transplantation, or ....





### Case Report Examples

## Self-directed Mindfulness Training and Improvement in Blood Pressure, Migraine Frequency, and Quality of Life

自我指导式的正念训练及改善高血压、偏头痛频率和生活质量

Formación autodirigida en la atención plena y mejora de la tensión arterial, la frecuencia de las migrañas y la calidad de vida

Erica B. Oberg, ND, MPH, United States; Margaret Rempe, PhD, United States; Ryan Bradley, ND, MPH, United States

Oberg E, Rempe M, Ryan B. Self-directed Mindfulness Training and Improvement in Blood Pressure, Migraine Frequency, and Quality of Life. *Global Adv Health Med*. 2013;2(2):20-25.



### Case Report and Research

### Practice-based Research



### Thalidomide in Pregnancy

SIR,—Congenital abnormalities are present in approximately 1.5% of babies. In recent months I have observed that the incidence of multiple severe abnormalities in babies delivered of women who were given the drug thalidomide ('Distaval') during pregnancy, as an antiemetic or as a sedative, to be almost 20%.

These abnormalities are present in structures developed from mesenchyme—i.e., the bones and musculature of the gut. Bony development seems to be affected in a very striking manner, resulting in polydactyly, syndactyly, and failure of development of long bones (abnormally short femora and radii).

Have any of your readers seen similar abnormalities in babies delivered of women who have taken this drug during pregnancy?

Hurstville, New South Wales.

W. G. McBride.



### Changes in FDA regulation



Scientific Writing in Health and Medicine



#### Randomized Controlled Trials

### Help establish Efficacy



### Case Reports

### Help establish Effectiveness



#### Evidence-Based Medicine



### External evidence and clinical expertise



### Case Reports in Medical Journals



45%

The number of published case reports increased by 45% from 49,918 in 2000 to 72,388 in 2010 on EMBASE and MEDLINE.



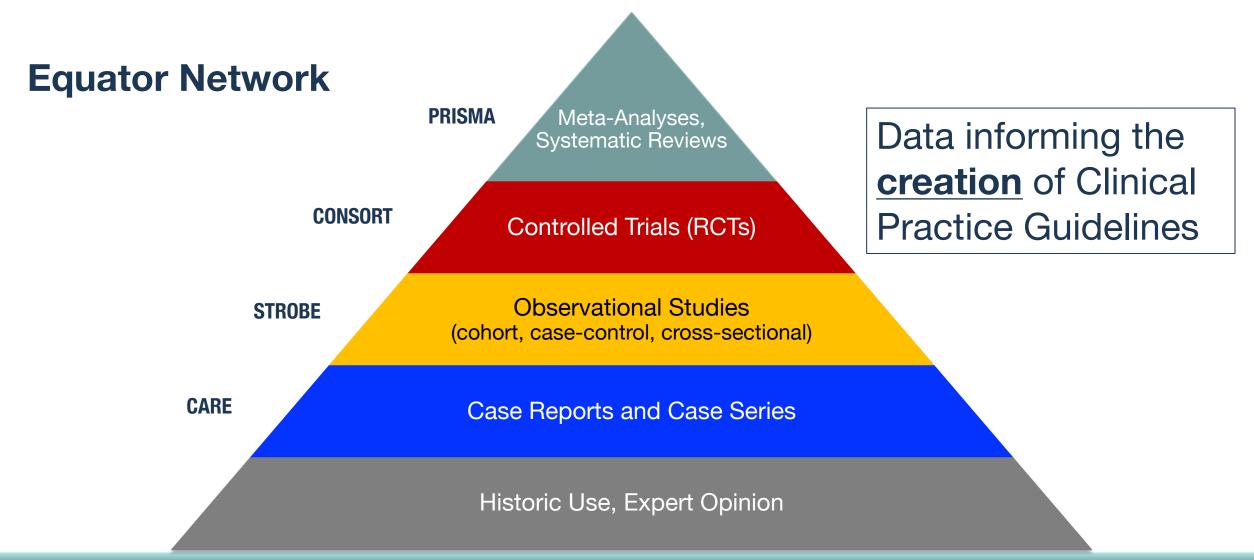
Some medical journals only publish case reports, such as *BMJ Case Reports* or the *Journal of Medical Case Reports*.







### Evidence-Based Medicine (EBM)



Scientific Writing in Health and Medicine



#### EBM and Clinical Practice Guidelines

Meta-Analyses, Systematic Reviews

Controlled Trials (RCTs)

Observational Studies (cohort, case-control, cross-sectional)

**Case Reports & Case Series** 

Historic Use, Expert Opinion

Case Reports offer feedback on Clinical Practice Guidelines

**CARE** guidelines

Case Reports

#### **Patient Data**

- Electronic Records
- Diagnostic reports
- Non-electronic data

**Healthcare Service Delivery** 



#### Evidence & Clinical Practice Guidelines



High quality evidence does not necessarily imply strong recommendations, and strong recommendations can arise from lower quality evidence. • •

• Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *British Medical Journal* 2008;336:924-926.



### Published Case Reports

- 1981 Morbidity and Mortality Weekly Report (MMWR): 5 case reports of patients with Pneumocystis pneumonia, early signals of AIDS.
  - Gottlieb M, Schanker H, Fan P, Saxon A, Weisman J, Pozalski I. Pneumocystis pneumonia LA. *Morbidity and Mortality Weekly Report* 1981.http://www.cdc.gov/mmwr/preview/mmwrhtml/june\_5.htm.

- 2008 New England Journal of Medicine: letter to the editor reporting on the successful treatment of infantile hemangioma with propranolol.
  - Leaute-Labreze C, Dumas de la Roque E, Hubiche T, Boralevi F, Thambo JB, Ta.eb A. Propranolol for severe hemangiomas of infancy. <u>N Engl J Med</u>. 2008;358(24):2649-51.



#### Healthcare Stakeholders



**Education institutions** 

**Policy makers** 



### Case Report Challenges

### Consistency and Completeness

- Kaszkin-Bettag M, Hildebrandt W. Case Reports on cancer therapies: improving reporting quality.
   Global Adv Health Med 2012:1(2); 8-10.
- Richason TP, Paulson SM, Lowenstein SR, Heard KJ. Case reports describing treatments in the emergency medicine literature: missing and misleading information. *BMC Emergency Medicine* 2009:Jun 15;9-10.



### Case Report Challenges

### Association versus Causal Relationships

- Kiene H, Hamre H, Kienle G. In support of clinical case reports: a system of causality assessment. Global Adv in Health Med 2013:2(2);76-87.
- Hauben M, Aronson JK. Gold standards in pharmaco-vigilance: the use of definitive anecdotal reports of adverse drug reactions as pure gold and high-grade ore. *Drug Saf* 2007:30(8); 645-55.



### Case Report Challenges

#### Risk of Bias



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### Introduction to CARE & Case Reports

### Thank you