The “Case Report” Controversy

Purvish M. Parikh
MD, DNB, FICP, PhD, ECMO
Prof & Head
Dept of Medical Oncology
Tata Memorial Hospital
purvish@rediffmail.com
A case report describes and discusses an instance of disease in a patient.

The essential characteristic of a publishable case report is educational value.

Writing case reports is one of the best ways to get started in medical writing. They are little mysteries that hold readers' interest and take less time to prepare.
The busy medical practitioner

Typical of Mumbai life
The Elephant Man
Neurofibromatosis

- Best known case report
- Described condition seen by many physicians and not considered worthy of reporting
- Led to
  - Two books
  - Award winning stage play
  - Successful Hollywood movie - starring Anthony Hopkins
Most case reports are on one of five topics:

• Unexpected association between diseases or symptoms. (Kaposi’s sarcoma and *Pneumocystis carinii* pneumonia in homosexual men in AIDS)

• Unexpected event in the Mx of a patient. (headache in a patient who handled TNT powder - transdermal absn of nitroglycerin and its dilating effect on blood vessels)

• Findings that shed new light on the possible pathogenesis.

• Unique or rare features of a disease.

• Unique therapeutic approaches.
Check list for Case Reports

✓ Introduction: rationale adequately explained & substantiated by references

✓ Case Description: brief, adequate & clear?

✓ Investigations: adequate & with normal values for uncommon ones

✓ Discussion: diagnosis and recommendations supported; potential issues refuted/ addressed
Features of a Case Report

- Medical information collected & presented on a single patient
- To highlight unique case, Rx or outcome
- Done by retrospective review of medical records
- Nothing is done for research purpose
- Statistics are not used
Case Report - Advantages

• Source of learning / inspiration for young
• Stimulates experienced clinicians
• Hypothesis generation for research
• Model for understanding symptoms
• 6000 – 7000 manuscript received annually
• 12 % published
• 108,500 circulation

• Patient needs to be involved closely in case report interactions - written informed consent using BMJ consent format
• Invite patient to comment on his/her own case and on experience of seeing medical debate unfold
• Patient / patient’s advocate to have access to emails and the web - esp. for discussion forum
“Uneasiness about publication of a detailed history”

Dora - identity ultimately discovered
Patient Risks

• Reader deduces pt’s identity & uses this info.

• Reader specifically makes effort to track down & expose identity

• Patient feels violated/ taken advantage of by doctor

• No written articles on this issue (IC) for case reports

• Psychoanalytic committee abandoned attempt to formulate policy about ICF

- 12 biomedical journal editors (inc. NEJM, BMJ, Lancet, JAMA)
- 1995 – protecting privacy and assuring anonymity
- 1997 – obtaining informed consent before publication

Patients rights to autonomy and privacy takes precedence over physicians need to contribute to the fund of (medical) knowledge.
• Clinical case reports on single patient is not research
• If more than one case included, becomes case series - is considered research and required ERB approval
• Informed consent of patient required for case report:
  - If patient deceased, authorisation not required
  - Waiver may be considered - only rarely
Johns Hopkins IRB Policy

Hopkins staff are not required to obtain IRB approval for case reports

Such a letter will be provided for submission to Medical journals

If the journal does not accept this decision, the issue is to be brought to the IRB Chair for resolution
Br J Psychiatry
Publication Policy 1995

- Consent should be taken
- When patient refuses, case study can be written up if pts anonymity maintained and confidentiality ensured

- Accept Risk of
  - Complaint by patient
  - Defamation charges wrt Breach of confidentiality
Expert opinion on the issue ......

Over 250 flights to 41 destinations in India!
Inconsistency of policy?

Medical Journal Editors’ actions:

In 2001, less than 3% of case reports in medical journals included statement that pts consent or ERB approval was obtained.
Laws/ Acts of interest

- Health Insurance Portability & Accountability Act, 1996 (HIPAA)
  US Dept of Health & Human Sciences

- Identifiable Personal Information (IPI)

- Personal Information Protection & Electronic Documents Act (PIPEDA)
  Canada 2000
Protection of Patients’ anonymity

• Name/ Initials/ Address
• Hospital No. / Unique Identifiers
• Dates
• Race/ Biometrics
• Pedigree/ Photographs
• Disguise identifying information
  - Patients’ characteristics
  - Personal history
Identify this patient?
When to take Informed Consent?

• Before writing manuscript
  - Pt. may be worried about final report
  - What if author does not complete report?

• After writing manuscript
  - If pt refuses
    • Authors efforts in vain
    • May resent refusal
    • Pt worried about saying “no”
  - If manuscript rejected
    • Informed consent in vain
    • Unnecessary mental trauma for patient
Solution !! ??

• Take IC after the case report is accepted for publication

• Limitation - puts author at risk of patient refusal
Written Informed Consent

- Eliminates risk of litigation
- Protects authors, journal & publishers

- Fails to protect patient from future negative personal consequences
HIPAA & Case Reports

- “A US based author .. “Unable to provide evidence that patient has consented because of new HIPAA privacy rule”

- “My mind exploded when I looked at HIPAA website ...the FAQ section seems to suggest that HIPAA should not interfere with case reports, but it’s not explicit”

Pritpal S Tamber, Medical Editor of BioMed Central
• Journals can be asked by patients to account for confidentiality of authorisation for 6 yrs!

• They have to guarantee that patients’ ICF have been kept confidential and secure

Faith McLellan
- Senior Editor, Lancet
- President, Council of Science Editors
HIPAA & Case Reports

- What about consent to be contacted in the future to obtain IC?
- Clause inserted in the General Consent (several pages of fine print that no one reads) that patients give permission to be contacted in the future to enroll them in research

- Real life HIPAA interpretation is quite more reasonable than some of the potentially most inconvenient hypothetical interpretations - Michael Callaham
• In defense of case reports and case series.

Vandenbroucke JP.
Leiden University Hospital Medical Center, Leiden, the Netherlands.
vdbroucke@mail.medfac.leidenuniv.nl

• Informed Consent for Case Reports - The Ethical Dilemma of Right to Privacy Versus Pedagogical Freedom

Stephen B. Levine and Susan J. Stagno.
Case Western Reserve University, Cleaveland, OH 44122
Risk of preventing Case Reports

- Data on epidemic diseases (SARS)
- Ever changing presentation of Manchausen’s syndrome
- Vulnerable patients reading about themselves
- Dementia/ Cognitive dysfunction - how IC?

Barriers to clinical teaching, research & publication
Lessons from timely Case Reports

• Emergency Mx of Malignant hyperthermia

• Recognition of fatal AEs of new drugs

• Tracheal intubation practices in severe Acute Respiratory Syndrome
Scientific Deceit

- Patient data that is altered or falsified
- Making up / inventing cases
- Combining elements from several lives into one case

"Hand me the Hairdryer"
Thank You
The Real Horror Story of HMOs

- Puts profit ahead of patients
- Do not exist to provide medical care
- Exists to make money by denying medical care

If we get all profit motives and outside administrators out of hospitals/doctors clinics, we can provide affordable health care for everyone