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Research Best Practices: Privacy, Information Risk Management and Compliance

Office of Continuing Professional Development Education
Research Series: November 2020

Brenda Manning, JD, CHC, CHPC – Compliance Director & Interim Privacy Officer
Robert Perry, MBA, MTM – CISO
Allison McKell, PhD, MPH – Research Compliance Specialist

Our mission is to improve the health of the communities we serve.



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Today's Objectives

- Describe considerations for patient/subject privacy in healthcare and in clinical research
- Navigate research-related data safety and risk management procedures at Carilion Clinic
- Summarize Carilion's new research Conflict of Interest (COI) process
- Recognize other research compliance topics



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Non-IRB Research Oversight: Who Are We?

- **Brenda Manning, JD, CHC, CHPC**
 - Compliance Director, Privacy
 - Interim Privacy Officer
 - Fun Fact: Worked on a ginseng farm
- **Robert (Rob) Perry, MBA, MTM**
 - Chief Information Security Officer
 - Fun Fact: Used to collect and restore old cars
- **Allison McKell, PhD, MPH**
 - Research Compliance Specialist
 - Interim Research Integrity Officer
 - Fun Fact: Worked with lemurs



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HIPAA Privacy & Research

10 THINGS RESEARCHERS SHOULD KNOW ABOUT PATIENT PRIVACY



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10 Things Researchers Should Know About Patient Privacy

- 1) The Privacy Office is your go-to resource for all HIPAA related questions and concerns
- 2) Patients are PEOPLE, not data or records
- 3) Patients care about their privacy
- 4) HIPAA is the “floor”
- 5) PHI consists of 18 HIPAA data elements
- 6) De-identified data contains none of the 18 HIPAA data elements
- 7) Limited Data Set is a term defined by HIPAA
- 8) Access to patient information is limited / defined by Carilion Policy / HIPAA
- 9) We are legally obligated to safeguard information in ALL FORMATS (electronic, paper and verbal)
- 10) Noncompliance can result in penalties for Carilion and the researcher



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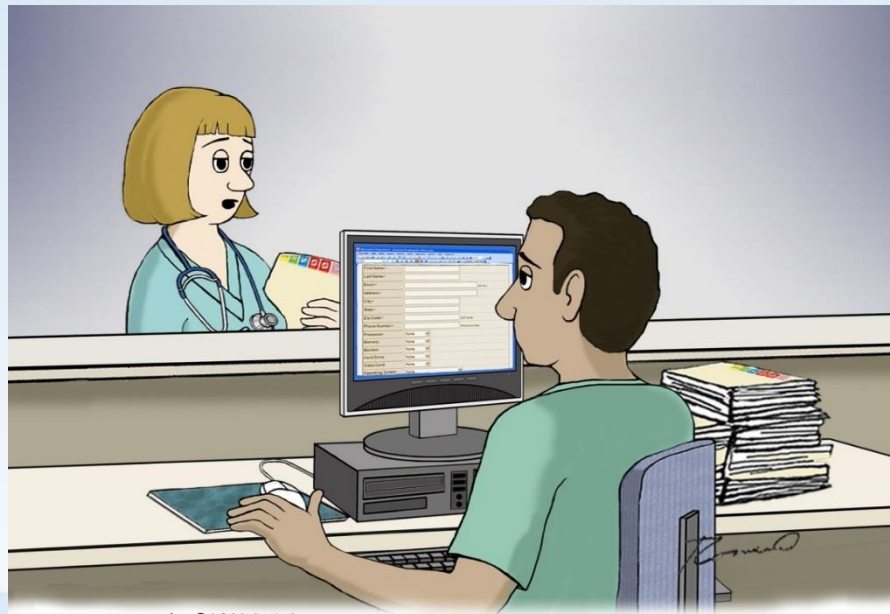


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#1 Partner With Privacy



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"Ask the Privacy Officer? No 'cause she'll tell me what the policies and procedures are. I'm looking for a way around them."

privacy@carilionclinic.org



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Privacy: Primary Functions

- 1) Staff Education
- 2) Consults on Projects System Wide
- 3) Business Associate Agreements
- 4) Assess / Mitigate Risk
- 5) Policy / Guideline Development
- 6) Investigate Privacy / Security Concerns
- 7) Serve as General Resource

Why do patient's share their PHI with us?

- Treat
- Diagnose
- Support



#2 Patients Are People, Not a Diagnosis or Data!



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In a 2016 study by Black Book, what percent of US patients state they withheld some medical information from their providers due to privacy/security concerns?

- a. 8%
- b. 32%
- c. 54%
- d. 89%



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#3 Patients Care About Their Privacy

In a 2016 study by Black Book, what percent of US patients state they withheld some medical information from their providers due to privacy/security concerns?

- a. 8%
- b. 32%
- c. 54%
- d. 89%

d. 89%



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#4 HIPAA: The privacy “floor”

– Federal Regulation

- *Health Insurance Portability and Accountability Act of 1996*
- Privacy and Security of Patient Information
- “Floor” in terms of patient privacy
 - Meaning other laws may be more restrictive
 - » e.g., State laws, Part 2



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HIPAA Privacy and Security Overview

Privacy Rule

- Addresses the **use** and **disclosure** of PHI
- Establishes privacy **rights** for individuals
- Requires appropriate safeguards for PHI in **all formats**: oral, paper, electronic

Security Rule

- Establishes national standards for **protecting ePHI** created, received used or maintained by covered entities
- Requires appropriate **administrative, physical and technical safeguards** to ensure confidentiality, integrity and availability of ePHI

Research activities may be subject to HIPAA



Who does HIPAA apply to?

– *Covered Entities*

- *a health plan, a health care clearinghouse, or a health care provider who engages in certain electronic transactions*

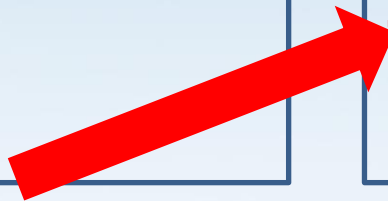
– *Business Associates of Covered Entities*



#5 PHI Consists of 18 HIPAA Identifiers

1. Names
2. Geographic information
3. Dates
4. Telephone numbers
5. Vehicle identifiers
6. Fax numbers
7. Device ID's / serial numbers
8. Email Addresses
9. Web URL's
10. SSN's

11. IP Addresses
12. MRN's
13. Biometrics
14. Health plan beneficiary numbers
- 15. Full face or comparable photos**
16. Account numbers
17. Certificate/license numbers
- 18. Any other unique identifier**





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What Is PHI?

Information about a patient's:

- Past, present, or future physical or mental condition,
- The provision of their healthcare or payment of it, and
- Somehow reasonably identifies the patient
 - Note that what is considered reasonable can change (e.g., 'Big Data,' AI, genomics)



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#6 De-identified Data Contains None of the 18 HIPAA Identifiers

De-Identified data $\neq$ PHI $\neq$ HIPAA

- **All** 18 identifiers must be removed, or de-identification may be established statistically.
- Generally you can use without restriction, but you should still ensure you have institutional approval.
- See PageCenterX for De-Identified Data policy



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#7 “Limited Data Set” is Defined by HIPAA

- **Limited Data Set = PHI**
- All HIPAA identifiers must be removed for the patient, their relative, employer or household member except:
 - Dates such as admission, discharge, service, date of birth and date of death;
 - City, state, five-digit zip code or more; and
 - Age in years, months or days or hours.
- Data Use Agreement (DUA) required
- See PageCenterX for Limited Data Set Policy



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I have Epic access, so why can't I have any data I want?





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#8 Access to PHI is defined by Carilion Policy

Access to Carilion Clinic's confidential information, including PHI, is a privilege, not a right.

If that access is abused, it may be taken away at any time

-See PageCenterX for TPO Policy and Epic Block Policy and access Guidelines



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Epic Use Policy

Permitted

- Accessing information necessary for your role:
 - Treatment,
 - Payment, or
 - Healthcare operations
 - Subject to the *Minimum Necessary Rule*: Only access the minimum amount of information to accomplish your purpose
- Viewing your own record

There is an audit trail of all user access



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Epic Use Policy

Not Permitted

- Accessing information not needed for our roles, including:
 - More than the minimum necessary amount of PHI to accomplish our purpose
 - Personal use
 - Snooping
- Accessing for education/learning purposes that are not part of a formal education program
- Accessing for quality assurance/improvement activities that are not part of a formal quality program or initiative
- Modifying your EHR
- Printing your EHR
- Signing your own RX
- Making your own appointments, checking yourself out, etc.
- Messaging your care team



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You can Access PHI for Research If:

- Your research protocol is Carilion Clinic IRB-approved
- Activities are approved as preparatory to research
- Additional requirements:
 - There are documented ACAs and background checks for any relevant research staff
 - Informed consent and/or HIPPA authorizations are properly obtained (or IRB-approved waivers)
 - There's an appropriate BAA and/or Data Use Agreement

Medical Research: Conducting medical research is an important part of Carilion Clinic's mission. Federal regulations permit use of your health information in medical research, either with your authorization or when the research study is reviewed and approved by an Institutional Review Board before the study begins. In some situations, limited information may be used before approval of the study to allow a researcher to determine whether enough patients exist to make a study scientifically valid. [From Carilion Clinic's NOPP](#)



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You Can Also Access PHI For:

- Education if the patient approves and you were directly involved in the patient's care or assigned a task
 - This often includes case studies or series (3 or fewer)
 - There is a patient authorization form for education
- QA/QI if ***formally assigned*** a task
- See Privacy Guidelines on PageCenterX for accessing PHI for Research, Education, QA/QI



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#9 We are Obligated to Safeguard PHI

- Safeguards are reasonable measures to limit incidental and prohibited uses and disclosures of PHI
- For Research, this means:
 - Following the 'Minimum Necessary Rule'
 - Only allowing approved personnel access to PHI
 - Only using approved data storage methods
 - Only using approved data transfer methods
 - Only using approved data analysis methods
- See Safeguard Policy on PageCenterX



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#10 Noncompliance May Result in Consequences for Carilion & Researchers

- Reputation Risk
- Disciplinary Action
- Epic Block
- Regulatory Enforcement
- Sanctions
- Licensing Board Action against those involved
- Maximum Annual HIPAA Financial Penalties
 - No knowledge: \$25,000
 - Reasonable cause, and not willful neglect: \$100,000
 - Willful neglect timely corrected (within 30 days): \$250,000
 - Willful neglect that is not timely corrected: \$1.5M
- Civil action– personally sued
- Criminal Penalties- Up to 10 years imprisonment



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Information Security at Carilion

DATA SAFETY AND RISK MANAGEMENT FOR RESEARCH



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InfoSec: Primary Functions

- 1) Cybersecurity
- 2) Vendor Risk Assessments
- 3) Consults on Projects System Wide
- 4) Assess / Mitigate Risk
- 5) Policy / Guideline Development
- 6) Investigate Security Concerns
- 7) Staff Education
- 8) Identity and Access Management



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Protect Your Access and Assets

- Do not share your passwords
- Intentional Sharing
- Tailgaters
- Phishing

Access & Confidentiality Agreement

Carilion Clinic has legal and ethical responsibilities to safeguard the privacy of its employees, students, and patients and their families and to protect the confidentiality of protected health information (PHI) and all other types of confidential information. Members of the Carilion Clinic community include but are not limited to: workforce members, members of the medical staff, extended community members, business associates, volunteers, students and vendors.

As a member of the Carilion Clinic, you agree to abide by Carilion Clinic policies regarding collected or maintained verbally,

Carilion Clinic's confidential information, student information, information gained by working with

GENERAL RULES

- I understand that it is my responsibility to protect confidential information, including P Resource policies, open information.
- I understand and accept the confidentiality of confidential information.
- I understand that Carilion Clinic will conduct a review of my confidential information.
- I will not modify my own confidential information. I will not use my confidential information for my family member.
- I will report to my supervisor any individual's or entity's confidential information.

PROTECTING CONFIDENTIAL INFORMATION

- I will not in any way access confidential information except as permitted by applicable Carilion Clinic policies.
- I will not photograph, video, or otherwise obtain prior approval for confidential information.
- I may not use or download confidential information, even in the personal premises in any form or for any purpose.
- I may only release patient information if I have received the release of patient information (PHI). If I have received the release of patient information (PHI) from my supervisor or HIM manager, I will release the information.
- I will dispose of confidential information and record retention in accordance with the policy.

USING ACCESS APPROPRIATELY

- I will access, use, and disclose confidential information only as authorized and needed to perform my assigned job duties.
- I will not use my Carilion Clinic authorized account(s) to access the health information or demographics (including addresses or birthdays) of my coworkers, other employees, friends, neighbors, or family members, including my spouse, parents, or children, unless that information is needed to perform my job duties. Unless it is impossible for another employee to provide the service or treatment, employees should not provide treatment or services to family members. Even with written/verbal permission or power of attorney, I cannot access my spouse or children's records with my Carilion Clinic access.
- I accept responsibility for all activities undertaken using my passwords, access code and other authorizations.
- It is my responsibility to log out of any system to which I have logged on. I will not leave unattended a computer to which I have logged on without first either locking it, or logging off the workstation.
- I agree to safeguard and not disclose my individual user identification passwords, access codes or any other authorizations that allow me to access Carilion Clinic confidential information to anyone; nor will I request access to, or use any other person's passwords or access codes.
- If I have reason to believe that the confidentiality of my password has been compromised, I will immediately change my password.
- I understand that individuals who access Carilion Clinic confidential information from home or other remote location must follow Carilion Clinic's policies and take precautions to keep information secure.

SIGNATURE

My signature below indicates that I have read, accept, and agree to abide by all of the requirements described above. I acknowledge that any violation of these requirements may result in disciplinary actions up to, and including, termination of employment and/or affiliation with Carilion Clinic.

Print Name: _____ Date: _____ ☐ Employee

Non-Employee Company Name: _____ ☐ Non-employee

Job Title: _____ Do you have access currently? _____

Carilion Badge Number: _____ Last 4 digits of your SSN: _____

Date of Birth (MM/DD): _____

Business Email Address: _____

Signature: _____

If you are not a Carilion Clinic employee, a copy of identification (driver's license or other) will be required.

Avoid Misdirected Communications

- Use secure authorized communication methods
- Verify email addresses
- Pick up printouts ASAP
- Use pre-programmed fax numbers



Don't multi-task when handling sensitive information

Texting Is Not Always Secure

- **No PHI using regular SMS/apps**
- No patient photos
- What can you text?
- Perfect Serve





Protect Your Electronic Devices

- Disabling security features put our devices at risk
- Always keep track of your devices!
- If working in public areas, get screen protectors and be aware of your surroundings
- Only access Carilion applications through secure networks
- Think carefully about personal use and follow the guidelines



Use Authorized Software and Devices

- Avoid downloading unapproved software or “Freeware”
- **Avoid uploading Carilion data onto unapproved websites**
- **Do not download Carilion data onto your personal device unless approved to do so**
- Is my personal Google Drive or Dropbox Secure?
- Portable hard drives or flash drives



Use Authorized Software and Devices

- Carilion Share Drives, RedCap, SPARC
- Carilion email accounts and encryption when not possible and no alternatives
- Follow Carilion video and teleconferencing guidelines
- Portable hard drives or flash drives must be encrypted and physically secured
- Password protect devices



The Vendor Risk Assessment Process

- Engage Information Security **EARLY**
- The full process takes a **minimum of 60=**
BUSINESS DAYS
 - This can often be longer due to work volumes and= vendor cooperation
 - Depending on level of risk, full process may not= always be needed
- There may already be tools and solutions= available that have been vetted
- For questions and consults, contact the Information Risk Management Team



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Research Compliance:

RESEARCH OVERSIGHT AND ETHICS



Compliance: Primary Functions

- 1) Staff Education
- 2) Research Conflicts of Interest
- 3) Consults on Projects System Wide
- 4) Assess / Mitigate Risk
- 5) Policy / Guideline Development
- 6) Investigate Privacy / Security Concerns
- 7) Serve as General Resource
- 8) Scientific Misconduct

Related but distinct from the HRPO and IRB



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Responsible Conduct of Research (RCR)

RESEARCH ETHICS



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Responsible Conduct of Research?

A collection of professional, regulatory, and ethical standards to guide the development, conduct, and reporting of scientific research.

<https://ori.hhs.gov/content/ori-introduction-responsible-conduct-research>



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Components of RCR

- The Protection of Human Subjects
- The Welfare of Laboratory Animals
- Conflicts of Interest
- Data acquisition, management, sharing, and ownership
- Mentoring
- Peer Review
- Publication Practices and Responsible Authorship
- Collaborative Science
- Research Misconduct



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Research Misconduct

From the U.S. Office of Science and Technology Policy (OSTP):

Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

<https://ori.hhs.gov/content/chapter-2-research-misconduct-federal-policies>



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- Fabrication → making up data or results and recording or reporting them
- Falsification → manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record
- Plagiarism → the appropriation of another person's ideas, processes, results, or words without giving appropriate credit



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Research Misconduct

From the U.S. Office of Science and Technology Policy (OSTP):

The actions must represent a significant departure from accepted practices; have been committed intentionally, or knowingly, or recklessly and be proven by a preponderance of evidence.

<https://ori.hhs.gov/content/chapter-2-research-misconduct-federal-policies>



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Research Misconduct

From the U.S. Office of Science and Technology Policy (OSTP):

*Does **NOT** include incidents of honest error or differences in opinion.*

<https://ori.hhs.gov/content/chapter-2-research-misconduct-federal-policies>



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Research Misconduct Procedures

- Institutions are responsible for reporting and investigating of reported instances of research misconduct.
- No retaliation against good faith reports.
- Allegations are not made public until they are fully investigated and confirmed.
 - Exception if threat to public health or safety

<https://ori.hhs.gov/content/chapter-2-research-misconduct-federal-policies>



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Consequences of Research Misconduct

- Professional
- Government Restrictions on Funding
- Retraction of Publications
- Personal and Institutional Loss of Reputation
- Downstream Wastes of Resources

<https://ori.hhs.gov/content/chapter-2-research-misconduct-federal-policies>



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“Who perpetrated this fraud? There is no doubt that it was Wakefield. Is it possible that he was wrong, but not dishonest: that he was so incompetent that he was unable to fairly describe the project, or to report even one of the 12 children’s cases accurately? No. A great deal of thought and effort must have gone into drafting the paper to achieve the results he wanted: the discrepancies all led in one direction; misreporting was gross.”

F Godlee, J Smith, and H Marcovitch. *BMJ*, (2011); Featured in article by Elisabeth Bik (<https://scienceintegritydigest.com/2019/06/17/falsification-the-andrew-wakefield-case/>)

Andrew Wakefield



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Andrew Wakefield

EARLY REPORT

Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years [range 3–10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Onset of behavioural symptoms was associated by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had intestinal abnormalities ranging from lymphoid nodular hyperplasia to granulomatous inflammation. Histology showed patchy chronic inflammation in 11 children and reactive ileitis in one. Lymphoid hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). There were no focal neurological abnormalities and EEG tests were normal. Abnormal laboratory results were significantly raised urinary methylmalonic acid compared with age-matched controls ($p=0.03$), low haemoglobin in four children, and low serum IgA in four children.

Interpretation The identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.

Lancet 1998; **351**: 637–41
See Commentary page

Inflammatory Bowel Disease Study Group, University Departments of Medicine and Histopathology (A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith) and the University Departments of Paediatric Gastroenterology

Introduction

We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and vomiting and, in some cases, food intolerance. We describe the clinical findings, and gastrointestinal features of these children.

Patients and methods

12 children, consecutively referred to a department of paediatric gastroenterology, had a history of a pervasive developmental disorder with loss of acquired skills and intestinal symptoms (abdominal pain, bloating and food intolerance), were investigated. All children were admitted to the ward from home, accompanied by their parents.

Clinical investigations

We took histories, including details of immunisations and exposure to infectious diseases, and assessed the children. In 11 cases, the histories were obtained by the senior clinician (JW-S). Neurological and psychiatric assessments were done by consultant staff (PH, MB) with HMS-4 criteria.¹ Developmental assessments included a review of prospective developmental records from parents, health visitors, and general practitioners. Four children did not undergo psychiatric assessment in hospital; all had been assessed professionally elsewhere, so these assessments were used as the basis for their behavioural diagnosis.

After bowel preparation, ileocolonoscopy was performed by SHM or MAT under sedation with midazolam and pethidine. Paired frozen and formalin-fixed mucosal biopsy samples were taken from the terminal ileum; ascending, transverse, descending, and sigmoid colons, and from the rectum. The procedure was recorded by video or still images, and were compared with images of the previous seven consecutive paediatric colonoscopies (four normal colonoscopies and three on children with ulcerative colitis), in which the physician reported normal appearances in the terminal ileum. Barium follow-through radiography was possible in some cases.

Also under sedation, cerebral magnetic resonance imaging (MRI), electroencephalography (EEG) including visual, brain stem auditory, and sensory evoked potentials (where compliance made these possible), and lumbar puncture were done.

Laboratory investigations

Thyroid function, serum long-chain fatty acids, and cerebrospinal-fluid lactate were measured to exclude known causes of childhood neurodegenerative disease. Urinary methylmalonic acid was measured in random urine samples from eight of the 12 children and 14 age-matched and sex-matched normal controls, by a modification of a technique described previously.² Chromatograms were scanned digitally on computer, to analyse the methylmalonic acid zones from cases

Published in 1998, a journalist's investigation led to the retraction of this infamous article in 2010.



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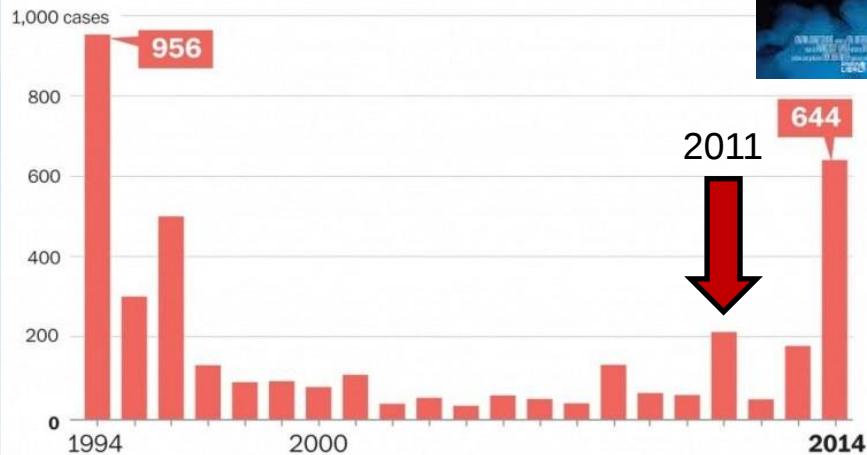


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- In **2011**, costs associated with measles outbreaks cost state and local governments \$2.7-\$5.3 million. *see arrow
- Does not reflect federal or societal (businesses, families, individuals) costs (~\$10k/patient).

Measles on the rise in the U.S.

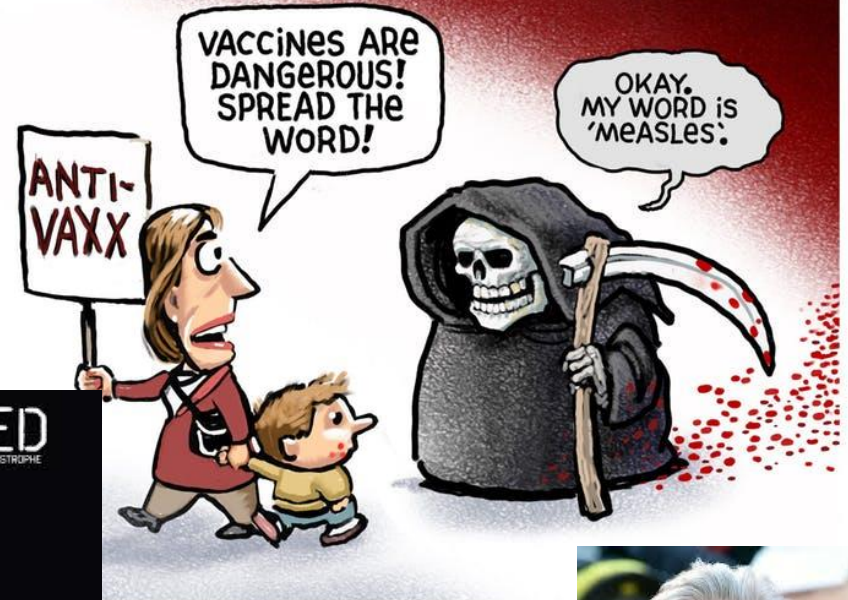
In 2014, 644 measles cases were reported, including a cluster of unvaccinated people in an Amish community in Ohio.



Source: Centers for Disease Control and Prevention

THE WASHINGTON POST

STAR TRIBUNE
SAC



- In 2017-2018 flu season, 85% of related pediatric deaths were in unvaccinated children.



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Vaccine

Volume 32, Issue 29, 17 June 2014, Pages 3623-3629



Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies

Luke E. Taylor, Amy L. Swerdfeger, Guy D. Eslick  

Science Summary: CDC Studies on Thimerosal in Vaccines

The evidence is clear: thimerosal is not a toxin in vaccines, but merely a preservative, preventing contamination, that has been used in vaccines for decades. This fact sheet provides a summary of thimerosal-related studies that were conducted by CDC or with CDC's involvement.

One More Time, With Big Data: Measles Vaccine Doesn't Cause Autism

A 10-year look at more than 600,000 children comes at a time when anti-vaccine suspicion is on the rise again.

evidence-based meta-analysis of case-control and cohort studies

Luke E. Taylor, Amy L. Swerdfeger, Guy D. Eslick

No MMR Vaccine-Autism Link in Large Study

Study of over 95,000 children included 15,000 unvaccinated 2 to 5 year olds and nearly 2,000 kids already considered at high risk for autism

April 21, 2015

The evidence is clear: thimerosal is not a toxin in vaccines, but merely a preservative, preventing contamination, that has been used in vaccines for decades. This fact sheet provides a summary of thimerosal-related studies that

THE JOURNAL OF PEDIATRICS • www.jpeds.com

ORIGINAL
ARTICLES

Increasing Exposure to Antibody-Stimulating Proteins and Polysaccharides in Vaccines Is Not Associated with Risk of Autism

Frank DeStefano, MD, MPH¹, Cristofer S. Price, ScM², and Eric S. Weintraub, MPH¹

One More Time, With Big Data: Measles Vaccine Doesn't Cause Autism

A 10-year look at more than 600,000 children comes at a time when anti-vaccine suspicion is on the rise again.

No MMR

Study of over
5 year olds
for autism

April 21, 2015



**Research \$
Public Health \$**

THE JOURNAL OF PEDIATRICS • www.jpeds.com

ORIGINAL
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Increasing Exposure to Antibody-Stimulating Proteins and Polysaccharides in Vaccines Is Not Associated with Risk of Autism

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Conflict of Interest

BRIEF REFRESHER



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What Is Conflict of Interest (COI)?



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What Is Conflict of Interest (COI)?

A situation in which an Investigator's, and/or their family member's financial, professional, or other personal consideration may directly or indirectly affect, or reasonably appear to affect, the Investigator's personal judgement in performing a Carilion Clinic-related duty or responsibility.



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A conflict of interest may be actual, apparent, or potential



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Why Is COI Disclosure Important?

- Transparency
- Research Integrity
- Research Subject Protection
- Required by Funding Agencies



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Why Is COI Disclosure Important?

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These concerns are also relevant to the business and your relationships with your patients



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Personal Anecdote About COI



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Potential Conflicts of Interest

- Employment
- Holding managerial positions
- Serving on advisory boards
- Receiving honorariums
- Having proprietary interest
- Having equity interest
- Receiving gifts—meals, travel, tangible goods



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Conflict of Interest

CASE STUDY



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Andrew Wakefield

EARLY REPORT

Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years [range 3–10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Onset of behavioural symptoms was associated by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had intestinal abnormalities ranging from lymphoid nodular hyperplasia to granulomatous inflammation. Histology showed patchy chronic inflammation in 11 children and reactive ileitis in one. Lymphoid hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). There were no focal neurological abnormalities and EEG tests were normal. Abnormal laboratory results were significantly raised urinary methylmalonic acid compared with age-matched controls ($p=0.03$), low haemoglobin in four children, and low serum IgA in four children.

Interpretation The identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.

Lancet 1998; **351**: 637–41
See Commentary page

Inflammatory Bowel Disease Study Group, University Departments of Medicine and Histopathology (A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith) and the University Departments of Paediatric Gastroenterology

Introduction

We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and vomiting, and, in some cases, food intolerance. We describe the clinical findings, and gastrointestinal features of these children.

Patients and methods

12 children, consecutively referred to a department of paediatric gastroenterology, had a history of a pervasive developmental disorder with loss of acquired skills and intestinal symptoms (abdominal pain, bloating and food intolerance), were investigated. All children were admitted to the ward from home, accompanied by their parents.

Clinical investigations

We took histories, including details of immunisations and exposure to infectious diseases, and assessed the children. In 11 cases, the histories were obtained by the senior clinician (JW-S). Neurological and psychiatric assessments were done by consultants (PH, MB) with HMS-4 criteria.¹ Developmental assessments included a review of prospective developmental records from parents, health visitors, and general practitioners. Four children did not undergo psychiatric assessment in hospital; all had been assessed professionally elsewhere, so these assessments were used as the basis for their behavioural diagnosis.

After bowel preparation, ileocolonoscopy was performed by SHM or MAT under sedation with midazolam and pethidine. Paired frozen and formalin-fixed mucosal biopsy samples were taken from the terminal ileum; ascending, transverse, descending, and sigmoid colons, and from the rectum. The procedure was recorded by video or still images, and were compared with images of the previous seven consecutive paediatric colonoscopies (four normal colonoscopies and three on children with ulcerative colitis), in which the physician reported normal appearances in the terminal ileum. Barium follow-through radiography was possible in some cases.

Also under sedation, cerebral magnetic resonance imaging (MRI), electroencephalography (EEG) including visual, brain stem auditory, and sensory evoked potentials (where compliance made these possible), and lumbar puncture were done.

Laboratory investigations

Thyroid function, serum long-chain fatty acids, and cerebrospinal-fluid lactate were measured to exclude known causes of childhood neurodegenerative disease. Urinary methylmalonic acid was measured in random urine samples from eight of the 12 children and 14 age-matched and sex-matched normal controls, by a modification of a technique described previously.² Chromatograms were scanned digitally on computer, to analyse the methylmalonic acid zones from cases

Published in 1998, a journalist's investigation led to the retraction of this infamous article in 2010.



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Managing COI in Research

Identification of a COI does not automatically disqualify someone from participating in research at Carilion.



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Managing COI in Research

- Identification of a COI will lead to further review by the CCO and CC Leadership



Managing COI in Research

- Identification of a COI will lead to further review by the CCO and CC Leadership
- A management plan may be implemented:
 - Public disclosure
 - Disclosure on consent forms
 - Appointment of an independent monitor
 - Modification of research protocol
 - Change of personnel and/or responsibilities
 - Reduction or elimination of financial interests



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Managing COI in Research

If COI cannot be managed, then a particular study may not receive administrative approval.



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Navigating Carilion COI

INSIGHT AND TIPS



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The COI Process for Research

- Is your investigator's study receiving non-Carilion funding or other support?



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The COI Process for Research

- Is your investigator's study receiving non-Carilion funding or other support?
- Is your investigator's study working with an external collaborator?



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The COI Process for Research

- Is your investigator's study receiving non-Carilion funding or other support?
- Is your investigator's study working with an external collaborator?
 - Are the collaborators providing equipment, reagents, supplies, services, etc.?



The COI Process for Research

- Is your investigator's study receiving non-Carilion funding or other support?
- Is your investigator's study working with an external collaborator?
 - What is the nature of the collaboration?
 - Are we or they subrecipients of funding?
 - Do they have an appropriate FCOI policy?

***Please reach out to me or ask the CRC/N to help with study with COI disclosure!**



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The COI Process for Research

- COI disclosures/revisions do not have to wait until the IRB application is turned in
- **HOWEVER**, study team members cannot perform research activities unless included as personnel on an IRB-approved protocol
- Request COI updates or direct study team members with COI questions to me

COI•SMART



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When events occur involving Carilion....

- As soon as you learn of a potential problem, you are required to report to the Privacy or Information Security Offices, so we can take steps to mitigate the risk and review the matter
- Depending on the research protocol, you may need to report to the HRPO/IRB as well
- You may need to report to home institution also
- Only share with those who need to know

Follow the Path of Integrity
CALL THE INTEGRITY HELP LINE FOR GUIDANCE

Ask questions or report integrity or compliance concerns to the Carilion Clinic Integrity Help Line:
844-732-6232
CarilionClinicIntegrity.org

Sometimes you may hear or see things that just don't feel right. That's when the Carilion Clinic Integrity Help Line can help. If you believe a workplace situation may violate a law, regulation, internal policy or standard, you can call or file an online report with the Help Line. And anonymous calls are just fine.

After you contact the Integrity Help Line, you'll receive a confidential case number and status update on the situation.

The best way to solve a situation is to discuss it. By starting the conversation, you are doing the right thing.

Call us or reach out to us online. We're here to make sure the right path is followed.

INTEGRITY **EXCELLENCE** **COMPLIANCE**

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When events occur involving Carilion....

- Contact information for our offices:
 - **Privacy Office**
 - Phone: (540) 510-4600
 - Email: privacy@carilionclinic.org & researchcompliance@carilionclinic.org
 - **HRPO/IRB**
 - Phone: (540) 769-7888
 - Email: irb@carilionclinic.org
 - **Information Security Office**

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Summary

- Privacy matters to patients/research subjects
- Only access, use, and disclose PHI for approved purposes
- Take reasonable precautions to secure PHI
- Use approved methods to store and use PHI
- Be mindful of the responsible conduct of research
- Research teams need current COI disclosures
- Engage us early in the process to avoid delays
- Contact our offices with questions / concerns



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Thank you!

Any Questions?