



Bioethics

ISSN: 2989-5448 (Online)

Publisher: Tomorrow's Research Publications (TRP)

An International Peer-Reviewed Open Access Journal

Policy Analysis

Genomic Incidental Findings: Duty to Disclose Versus Duty to Protect

Astrid Mendes^{1*}, Camille Papadopoulos² and Pieter Sorensen¹¹Department of Bioethics, Jutland University Centre for Bioethics, Denmark²Center for Medical Ethics and Law, Northmoor School of Public Health Ethics, United Kingdom³Department of Bioethics, Jutland University Centre for Bioethics, Denmark

ABSTRACT

Genomic sequencing routinely uncovers findings unrelated to the reason testing was ordered, forcing clinicians, researchers, and courts to weigh a duty to disclose information that could prevent harm against a duty to protect patients, participants, and third parties from information they did not seek and may not want.

This review traces how that tension has been managed across four settings: clinical exome and genome sequencing under the ACMG's evolving secondary findings recommendations, research biobanking, disclosure obligations toward biological relatives following cases such as *ABC v St George's*, and pediatric sequencing, where the person most affected cannot yet consent.

Across these settings, the clearest point of convergence is that clinical actionability, rather than novelty or scientific interest, should trigger disclosure, while the least settled question is what is owed to people, chiefly relatives, who were never tested at all.

We argue that actionability thresholds, family notification protocols, and pediatric-specific safeguards should be treated as related but distinct policy problems rather than folded into a single incidental-findings policy.

The review concludes that defensible institutional practice requires calibrating disclosure obligations to actionability and life stage rather than adopting a uniform rule for all incidental genomic findings.

Keywords: incidental findings; secondary findings; genomic sequencing; duty to warn; research ethics

Citation: Mendes A, Papadopoulos C and Sorensen P (2024) Genomic Incidental Findings: Duty to Disclose Versus Duty to Protect. *Bioethics*. 1(2):01-05.

Corresponding Author: Astrid Mendes

E-mail Address: a.mendes@jucb.dk

Article History: Received 03 June 2024 | Accepted 01 September 2024 | Published 10 December 2024

Copyright: © 2024 Astrid Mendes, et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited (<https://creativecommons.org/licenses/by/4.0/>).

INTRODUCTION

Every large-scale sequencing effort eventually turns up something nobody was looking for. A panel ordered to investigate a child's unexplained seizures returns a

pathogenic *BRCA1* variant with no bearing on the seizures at all; a research cohort assembled to study cardiovascular risk factors incidentally flags a handful of participants carrying variants for Lynch syndrome. These incidental findings, sometimes now separated

in the literature from deliberately sought "secondary findings," sit at the center of one of clinical genomics' more durable disputes: does the person who generated the data thereby acquire an obligation to hand it over, or does handing it over risk doing the kind of harm that medicine is supposed to avoid [1]?

The dispute is not merely academic. The American College of Medical Genetics and Genomics (ACMG) has, since 2013, maintained a list of genes it recommends laboratories screen for and report regardless of the original reason for testing, a list that has been revised repeatedly as the underlying evidence about penetrance and actionability has shifted [2]. Each revision reopens the same argument: that a genomics laboratory which possesses information capable of preventing serious harm may be under something closer to a moral obligation to look for it, not merely a permission to disclose it if stumbled upon [3]. Set against this is a much older clinical norm, the recognized right not to know, along with a practical worry that indiscriminate disclosure of findings of uncertain significance will produce anxiety, unnecessary follow-up testing, and downstream costs disproportionate to any benefit gained [4]. This paper examines how that tension has actually been managed across four settings where it becomes concrete: clinical exome and genome sequencing under professional guidelines, research biobanking, disclosure obligations toward biological relatives, and pediatric sequencing, where the person whose future is most at stake cannot yet consent to anything.

THE ACMG SECONDARY FINDINGS LIST AND THE LOGIC OF OPPORTUNISTIC SCREENING

The ACMG's original 2013 recommendation broke with decades of genetic-counseling orthodoxy by directing laboratories to report certain findings even over a patient's objection, on the reasoning that some risks -- inherited cancer syndromes and cardiac arrhythmia genes chief among them -- are serious, medically actionable, and cheap to flag once whole-exome or whole-genome data already exists [1]. The list has since grown and been refined through several policy updates, most recently version 3.0, which added conditions after weighing newly available penetrance data against the burden false positives place on both patients and health systems [2]. What makes this approach distinctive, and controversial, is that it treats disclosure less as something owed to the individual who happened to be sequenced and more as an artifact of what became technically visible once sequencing was performed for an unrelated reason.

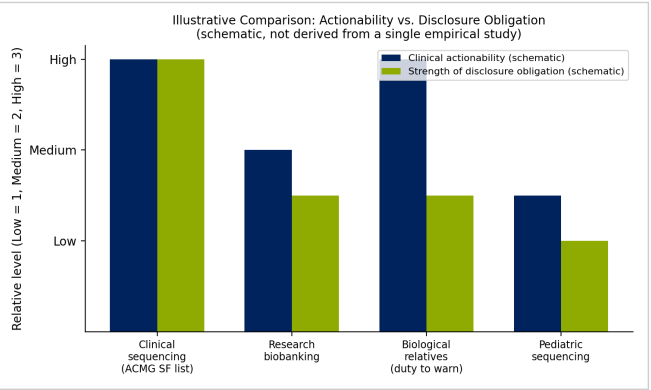
Ballantyne and colleagues push this reasoning further, arguing that researchers conducting large-scale genomic studies may be morally required to actively search for medically actionable secondary findings among their data, not merely report what they happen to notice, precisely because the marginal cost of

looking is now so low relative to the benefit a warned patient might receive [3]. A qualitative study of clinicians, laboratory scientists, and patients surfaced a more layered picture of what actually justifies disclosure in practice: not a single value like beneficence, but a cluster involving actionability, family relevance, and respect for the original reason testing was ordered, weighted differently by different stakeholders [5]. Table 1 sets out how the main competing considerations line up across these four contexts, and Figure 1 offers a schematic illustration of how disclosure obligations tend to strengthen as clinical actionability increases, an intuition that runs through most of the professional guidance discussed here even though it is rarely made explicit in a single document.

Table 1. Competing considerations shaping disclosure obligations across four genomic contexts discussed in this review.

Context	Primary duty invoked	Main countervailing concern	Governing anchor
Clinical exome/genome sequencing	Duty to disclose medically actionable secondary findings	Patient's right not to know; false-positive burden	ACMG SF list (evolving)
Research biobanking	Duty to return findings of high analytic validity and clinical significance	No treating relationship; recontact often infeasible	Institutional /IRB policy, still uneven
Biological relatives	Emerging duty to warn of serious, preventable familial risk	Duty of confidentiality to the original patient	Case law (e.g. ABC v St George's)
Pediatric sequencing	Parental authority to receive relevant findings	Child's future autonomy / right to an open future	Professional guidelines, jurisdiction-dependent

Figure 1. Schematic illustration of how the strength of a disclosure obligation tends to track clinical actionability across the four contexts discussed in this review. This is an illustrative synthesis of the qualitative pattern in the literature, not a measurement from a single empirical study.



INCIDENTAL FINDINGS IN RESEARCH BIOBANKING

Research biobanks face a version of this problem that is structurally different from the clinical setting, because the relationship between researcher and participant was never framed as a treating relationship in the first place. Wolf and colleagues, writing two influential analyses roughly contemporaneously, argued that researchers nonetheless incur some obligation to participants when findings meet a threshold of analytic validity and clinical significance, but that the threshold should be set considerably higher than in clinical care, given that research protocols are not typically built with the infrastructure to verify, counsel on, or act upon incidental findings [6]. Their companion analysis focused specifically on biobanks and archived datasets, where the difficulty compounds: samples may have been collected years earlier under consent language that never anticipated genomic reanalysis, and the original participant may be difficult or impossible to recontact [7].

Holm and Ploug took a more skeptical position, contending that biobank-wide policies on incidental findings were, as of their analysis, premature, because the field had not yet settled basic questions about which findings warrant action, whose job it is to verify them, and who bears the cost -- rushing to a uniform policy risked enshrining answers to those questions before the evidence justified them [8]. That caution has not been fully vindicated by subsequent practice: a 2023 consensus statement from a German biobank working group set out a concrete, hospital-based workflow for handling incidental findings, suggesting that at least some parts of the field have moved past the point of waiting for full consensus and started building the operational infrastructure that Wolf's analyses said was missing [9]. The persistent gap between these two positions -- caution about premature policy versus the practical need for some working procedure -- is itself informative about how unevenly this area of ethics has matured relative to the underlying genomic technology.

FAMILY MEMBERS, CONFIDENTIALITY, AND THE EMERGING DUTY TO WARN

A genome is not information about one person; it is, by construction, partial information about that person's biological relatives, who never consented to anything and may not even know a relevant test was performed. Thorogood and colleagues describe this as one of the more intractable features of genomic testing generally, since ordinary models of medical confidentiality assume information belongs to the patient who generated it, an assumption genomic data only partially satisfies [10]. Dheensa and colleagues, drawing on qualitative interviews with UK genetics professionals, found that clinicians already navigate this tension informally and inconsistently, often encouraging patients to inform relatives themselves rather than relying on a clear institutional policy for when a clinician should intervene directly [11].

The English case of *ABC v St George's Healthcare NHS Trust* forced the underlying question into a courtroom: a woman argued that clinicians owed her a duty of care to disclose her father's Huntington's disease diagnosis, since it bore directly on her own reproductive decisions, even though the diagnosis was her father's confidential medical information [12]. The Court of Appeal accepted, in principle, that health professionals could owe a duty of care to at-risk relatives in some circumstances, without going so far as to establish an unqualified duty to warn in every case, leaving genetics services to work out where the line falls in practice [13]. Commentary since the ruling has been split between those who read it as a narrow, fact-specific decision and those who see it as the beginning of a broader legal duty of care within clinical genetics [14]. Gilbar and Barnoy go further still, arguing on comparative grounds that failure to warn relatives of a serious, actionable genetic risk should sound in tort as a legal wrong in its own right, not merely an ethical lapse [15]. Foster and Herring, by contrast, frame the dispute as a genuine conflict between two legitimate duties -- confidentiality to the patient and protection of third parties -- rather than one that automatically resolves in favor of disclosure, and argue that any workable rule has to specify how serious and how preventable the harm must be before confidentiality yields [16]. Parker's analysis of the underlying "fair, just and reasonable" test used in English negligence law reaches a similar conclusion: a duty to warn relatives is legally arguable, but its boundaries remain genuinely unsettled rather than merely under-enforced [17].

PEDIATRIC SEQUENCING AND FINDINGS THE CHILD CANNOT YET CONSENT TO

Children present the sharpest version of the disclosure dilemma because the person whose genomic information is at issue cannot yet exercise the autonomy that much of adult consent doctrine assumes. Ormond and colleagues' systematic qualitative review of ethical issues in pediatric genome-wide sequencing found recurring tension between parents' authority to make decisions on a child's behalf and a distinct value, sometimes called the child's "right to an open future," which counsels against disclosing findings relevant only to adult-onset conditions the child cannot yet meaningfully engage with [18]. Botkin frames the same problem in starker terms: parental requests to learn a child's carrier status for a late-onset condition, or the results of predictive testing for an adult-onset disease, run directly against the child's own future interest in deciding for themselves whether to know [19].

Robertson and colleagues' 2023 guidelines specifically address the harder case of unsolicited findings discovered during sequencing ordered for a child's developmental delay, recommending a return-of-results process calibrated to a finding's

actionability during childhood rather than to its general clinical significance [20]. Malek's review of national and professional policy statements found meaningful divergence across jurisdictions on exactly this point -- some frameworks default toward disclosure whenever a finding is medically actionable at any life stage, others withhold anything not actionable within childhood -- meaning that the same incidental finding in a child could be handled quite differently depending on where the sequencing took place [21]. A more recent synthesis frames secondary findings less as an unwanted by-product of sequencing and more as a resource to be actively shared once appropriate consent and counseling infrastructure exists, a framing that, if adopted broadly, would push pediatric policy further toward disclosure than the "right to an open future" literature has generally been willing to go [22]. Institutional review boards themselves remain divided on how far this obligation extends in the research setting: a survey of IRB members found substantial disagreement over whether researchers are obligated to actively search for incidental findings in pediatric research cohorts at all, echoing the broader biobanking debate discussed above [23].

CONCLUSION

No single principle cleanly resolves the tension between a duty to disclose and a duty to protect, because the two duties are not really in competition across the board; they trade off differently depending on how actionable a finding is, whose interests are affected beyond the person tested, and how much capacity that person has to decide for themselves. The clearest area of convergence across the literature reviewed here is that actionability, not novelty or scientific interest, is what should trigger disclosure -- a principle the ACMG's evolving secondary findings list embodies for clinical sequencing, that biobank ethics increasingly borrows for research contexts, and that pediatric guidelines apply more cautiously given a child's undeveloped capacity to consent. The least settled area, by contrast, is what obligations run toward people who were never tested at all -- biological relatives whose risk is implicated by someone else's result -- where legal doctrine following *ABC v St George's* has opened the door to a duty of care without yet specifying its boundaries. Institutions building disclosure policy going forward would do well to treat actionability thresholds, family notification protocols, and pediatric-specific safeguards as three related but distinct problems, rather than assuming a single incidental-findings policy can adequately answer all three.

DECLARATIONS

Acknowledgements

The authors are grateful to colleagues at their respective institutions for helpful discussion during the drafting of this review.

Funding

This review received no external funding.

Conflict of Interest

The authors declare no conflicts of interest relevant to this work.

Author Contributions

Astrid Mendes conceived the review, drafted the introduction and the section on the ACMG secondary findings framework, and coordinated revisions. Camille Papadopoulos performed the literature synthesis on research biobanking and family disclosure obligations and critically revised the manuscript. Pieter Sorensen contributed the section on pediatric sequencing, prepared the table and figure, and gave final approval of the submitted version. All authors read and approved the final manuscript.

Ethics Statement

As a literature review synthesizing previously published, publicly available research and policy analysis, this article did not involve new data collection from human participants and did not require institutional ethics committee approval.

Data Availability

No new data were generated or analyzed for this review. All sources discussed are cited in the reference list and are publicly available through their respective publishers.

REFERENCES

1. Green RC, Berg JS, Grody WW, et al. (2013) ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing. *Genetics in Medicine*, PMID:23788249.
2. Miller DT, Lee K, Chung WK, et al. (2021) ACMG SF v3.0 list for reporting of secondary findings in clinical exome and genome sequencing: a policy statement of the American College of Medical Genetics and Genomics (ACMG). *Genetics in Medicine*, DOI:10.1038/s41436-021-01147-0.
3. Ballantyne A, Newson AJ, Ackerman S (2019) Why genomics researchers are sometimes morally required to hunt for secondary findings. *AJOB Empirical Bioethics*, PMID:31958402.
4. Ravitsky V (2003) Timing of prenatal diagnosis, parental autonomy, and the right not to know. *Journal of Medical Ethics*.
5. Ackermann K, et al. (2020) Ethical values supporting the disclosure of incidental and secondary findings in clinical genomic testing: a qualitative study. *BMC Medical Ethics*, DOI:10.1186/s12910-020-0452-0.
6. Wolf SM, Lawrenz FP, Nelson CA, et al. (2012) Managing incidental findings in human subjects

- research: analysis and recommendations. *Journal of Law, Medicine & Ethics*, PMID:22375919.
7. Wolf SM, et al. (2012) Managing incidental findings and research results in genomic research involving biobanks and archived data sets. *Genetics in Medicine*, PMID:22436882.
8. Holm S, Ploug T (2014) Incidental findings: the time is not yet ripe for a policy for biobanks. *BMC Medical Genetics*, PMID:24568220.
9. GBA/GBN Working Group (2023) GBA/GBN-position on the feedback of incidental findings in biobank-based research: consensus-based workflow for hospital-based biobanks. *BMC Medical Ethics*.
10. Thorogood A, Cook-Deegan R, Knoppers BM (2019) The new world of genomic testing and family privacy. *Genetics in Medicine*, PMID:26312112.
11. Dheensa S, Fenwick A, Lucassen A (2016) Familial genetic risks: how can we better navigate patient confidentiality and appropriate risk disclosure to relatives? *Journal of Medical Ethics*, PMID:27852898.
12. ABC v St George's Healthcare NHS Trust: exercising judgment without fear (2020) Progress Educational Trust.
13. After ABC v St George's: a new duty to consider (2020) PHG Foundation blog.
14. Rantanen E, et al. (2020) Professional duties are now considered legal duties of care within genomic medicine. *European Journal of Human Genetics*, DOI:[10.1038/s41431-020-0663-3](https://doi.org/10.1038/s41431-020-0663-3).
15. Gilbar R, Barnoy S (2019) Non-disclosure of genetic risks: the case for developing legal wrongs. *Journal of Law and the Biosciences*, PMID:31938535.
16. Foster C, Herring J (2019) Striking a balance: resolving conflicts between the duty of confidentiality and duties to third parties in genetics. *Legal Studies*, DOI:[10.1017/lst.2019.14](https://doi.org/10.1017/lst.2019.14).
17. Parker M (2019) A duty to warn relatives in clinical genetics: arguably 'fair, just and reasonable'. *Journal of Law and Medicine*.
18. Ormond KE, Bombard Y, et al. (2021) The full spectrum of ethical issues in pediatric genome-wide sequencing: a systematic qualitative review. *Genetics in Medicine*, PMID:34210952.
19. Botkin JR (2018) Ethical conundrums in pediatric genomics. *Hematology, American Society of Hematology Education Program*.
20. Robertson N, et al. (2023) Uncertain futures and unsolicited findings in pediatric genomic sequencing: guidelines for return of results in cases of developmental delay. *European Journal of Human Genetics*, PMID:37951889.
21. Malek J (2017) Genomic testing in the paediatric population: ethical considerations in light of recent policy statements. *Molecular Diagnosis & Therapy*, DOI:[10.1007/s40291-016-0210-7](https://doi.org/10.1007/s40291-016-0210-7).
22. Knoppers BM, Joly Y (2022) Genomic tools for health: secondary findings as findings to be shared. *Human Genetics*.
23. Downing NR, et al. (2016) IRB perspectives on obligations to disclose genetic incidental findings to research participants. *Genetics in Medicine*, PMID:26866580.