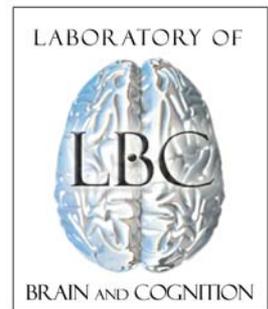


# Issues Regarding the Management of Incidental Findings in Neuroimaging

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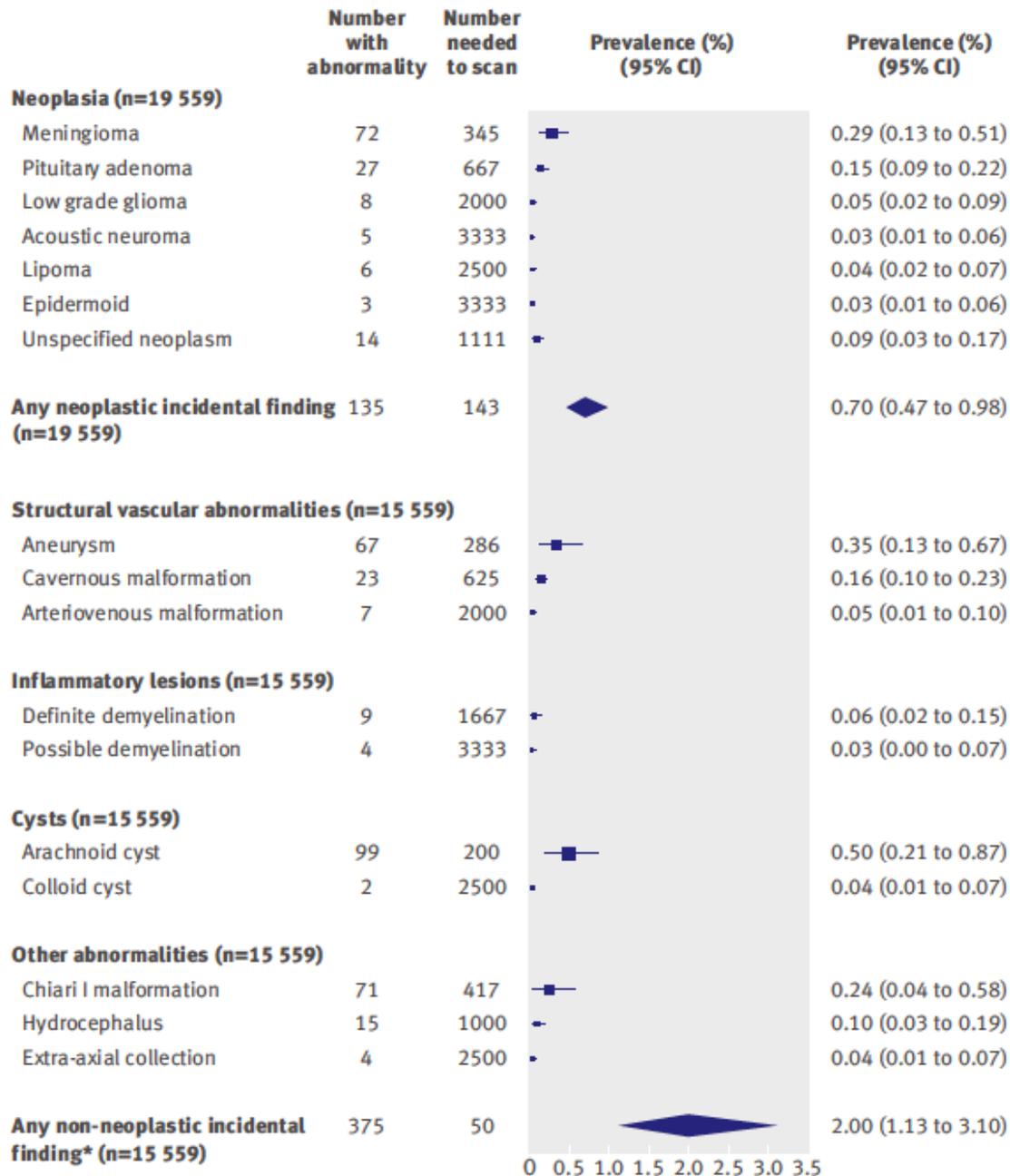


## What is the primary issue?

About 2% of normal research volunteers have an incidental finding of clinical significance, and it is unknown how many truly benefit from follow-up. What should be done procedurally?

## What are the related issues?

- Active brain screening can be expensive, and has no clear benefit over treatment following symptoms.
- False positives are a risk, and have deleterious impact on otherwise normal subjects.
- Most research scans are not “clinical-grade” therefore difficult to interpret.
- Most researchers are not qualified to read scans for diagnoses.
- The prevalence of lifelong asymptomatic individuals with lesions/tumors is unknown.



*Z. Morris et al, BMJ 2009;339:b3016*

**Fig 1 | Prevalence of some incidental findings (\*excluding white matter hyperintensities, microbleeds, and silent infarcts) on brain magnetic resonance imaging**

TABLE. Incidental Findings on 2000 MRI Scans

Finding <sup>a</sup>	No. (%)
<b>Tumors</b>	
Meningioma	18 (0.9)
Pituitary adenoma	6 (0.3)
Vestibular schwannoma	4 (0.2)
Trigeminal schwannoma	1 (<0.1)
Intracranial lipoma	2 (0.1)
High- or low-grade glioma	1 (0.1)
Metastases	1 (0.1)
<b>Vascular findings</b>	
Asymptomatic brain infarct	145 (7.2)
Aneurysm	35 (1.8)
Cavernous angioma	7 (0.4)
Major vessel stenosis	9 (0.5)
Subdural hematoma	1 (<0.1)
<b>Other findings</b>	
Arachnoid cyst	22 (1.1)
Dermoid cyst	1 (<0.1)
Type I Chiari malformation	18 (0.9)
Fibrous dysplasia	1 (<0.1)

<sup>a</sup> Diagnoses were based on imaging only, without histologic confirmation. Data from reference 1.

*R. J. Komotar, et al. Mayo Clin Proc.  
May 2008, 83(5): 563-565*

“...researchers who obtain consent from volunteers, should provide information about the prevalence of incidental brain findings on brain MRI, the higher prevalence with high resolution MRI sequences, and the shortage of evidence to inform their management.”

*Z. Morris et al, BMJ 2009;339:b3016*

“Brain MRI screening of asymptomatic patients regardless of age, health, or medical history is an example of an ineffective screening program that would produce many inconsequential findings and an exceedingly low rate of clinically relevant findings. Valuable screening programs must either address a highly prevalent disease or be applied to high-risk individuals, and must accurately uncover a treatable disease.”

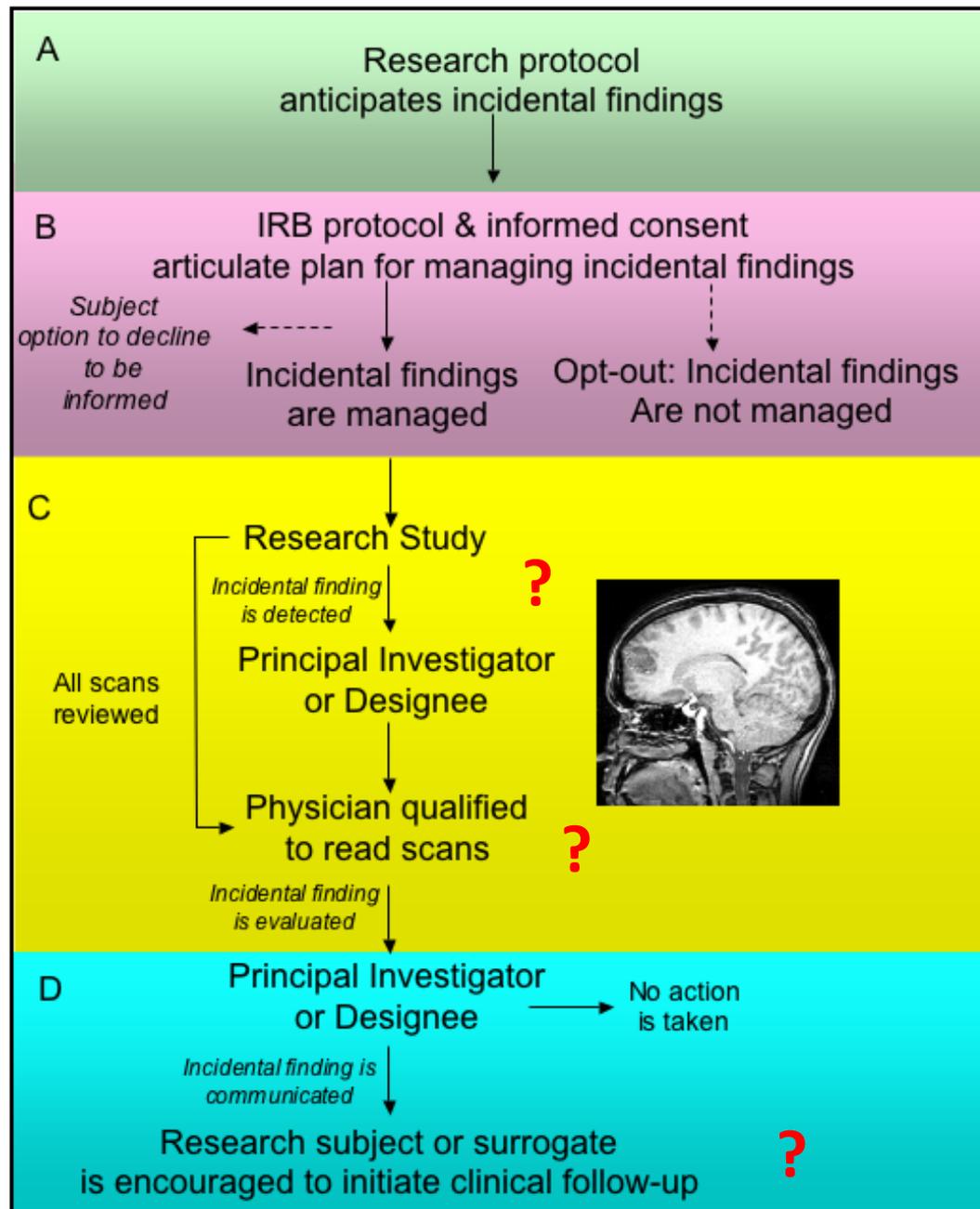
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## Possible Solutions...presented another way

Option	Implications/applications
1. No action is taken beyond articulating a plan for handling incidental findings in the informed consent process.	Researchers do not have an obligation to actively screen for incidental findings, only to have a plan in place if an incidental finding is detected. With this option, researchers inform the participants that the scans will not be examined for abnormalities. This approach might be appropriate in those settings, and for those research protocols, in which the images obtained are not of sufficient resolution or quality to provide a basis for reliably detecting an atypical finding.
2. Participants are informed that if a suspicious finding is discovered it will be reported to them, but images are not reviewed by an expert trained to perform a clinical evaluation.	This might be the approach of choice if the research team does not include personnel with the expertise to perform clinical analysis of a suspicious scan or does not have a pathway for obtaining a clinical evaluation.
3. Expert review of scans with a medically suspicious abnormality is performed prior to communication to the participant.	Subjects are informed that incidental findings of potential clinical significance will receive expert review and the finding will be reported to them if the review indicates that clinical follow-up is warranted. This option requires the inclusion of an expert on the research team or the use of a consultant for expert clinical evaluation.
4. Expert review of research scans is performed routinely; incidental findings that may have clinical significance are communicated.	This option entails a clinical read of all research scans. This differs from the option above in that all research scans in the study will be subject to clinical evaluation, not just those identified as presenting a possible incidental finding. Because this option necessitates a significant time commitment for a clinician, it is likely most practical for research conducted in a clinical setting.
5. Both research and clinical-grade images are routinely acquired; incidental findings that may have clinical significance determined by expert review are communicated.	This approach may require longer scanning times or multiple scan sessions. This is the most resource-intensive of the options considered and is likely to be practical only in a clinical setting.

J. Illes, M. P. Kirschen, E. Edwards, P. Bandettini, M.K. Cho, P. J. Ford, G. H. Glover, J. Kulynych, R. Macklin, D. B. Michael, S. M. Wolf, T. Grabowski, B. Seto, Practical approaches to incidental findings in brain imaging research, *Neurology*, 70, 384-390 (2008).

# Several Possible Solutions



# Framing the challenge

*On one hand*, we want to catch anything that may be significant to the health of the subject.

*On the other hand*, what exactly would justify added cost & burden, risk of false positives?...as well as the fact that the overall effectiveness of screening is unclear.

*What incidence rate would justify what effort – even an effort of limited effectiveness and clear risks?*