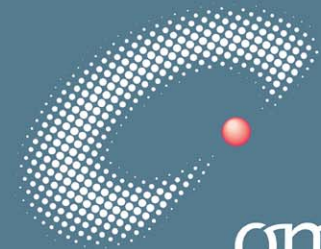


The impact of guidance on regulation and governance on the ability and willingness of pathologists to conduct research.

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Dr Brian Clark  
Difficulties With and Solutions to  
Pathologists' Engagement with Research  
Cardiff, 3<sup>rd</sup> July 2009



# Background

- Frequent anecdotal reports that the regulatory and governance environment relating to:
  - the involvement of NHS patients in research;
  - the use of human biological samples in research;
  - the use of personal and health information in research; and,
  - the need to gain NHS Research & Development office and Research Ethics Committee approvals
- are affecting the willingness and ability of **pathologists** to lead research or contribute to research.
- Could this be substantiated by collecting quantitative evidence?

# Aims

- onCore UK conducted a survey that:
  - aimed specifically to gauge the **diversity, availability** and **utility of guidance** that purports to assist researchers navigate the regulatory and governance environment.
  - made an assessment of the overall opinion of the regulatory and governance environment
  - compared the opinions of pathologists with other professional groups.

# Methods

- Cross sectional survey was conducted as a participant-completed questionnaire study.
- Responses were welcomed over a 2 week period in February 2009.
- Open to responses and widely disseminated via a variety of august UK bodies:
  - Pathological Society,
  - Royal College of Pathologists,
  - National Cancer Research Institute,
  - National Cancer Research Network,
  - Experimental Cancer Medicine Network.

# Subgroup analysis

- The subgroups investigated included:
  - those working in pathology laboratories (consultant pathologists, trainee pathologists, clinical scientists in pathology and biomedical scientists).
  - those who are currently active in *human tissue or biological sample research* in comparison to those who are not.
    - those working in the NHS, in academia or in combined NHS/University roles.



# Overview of respondents

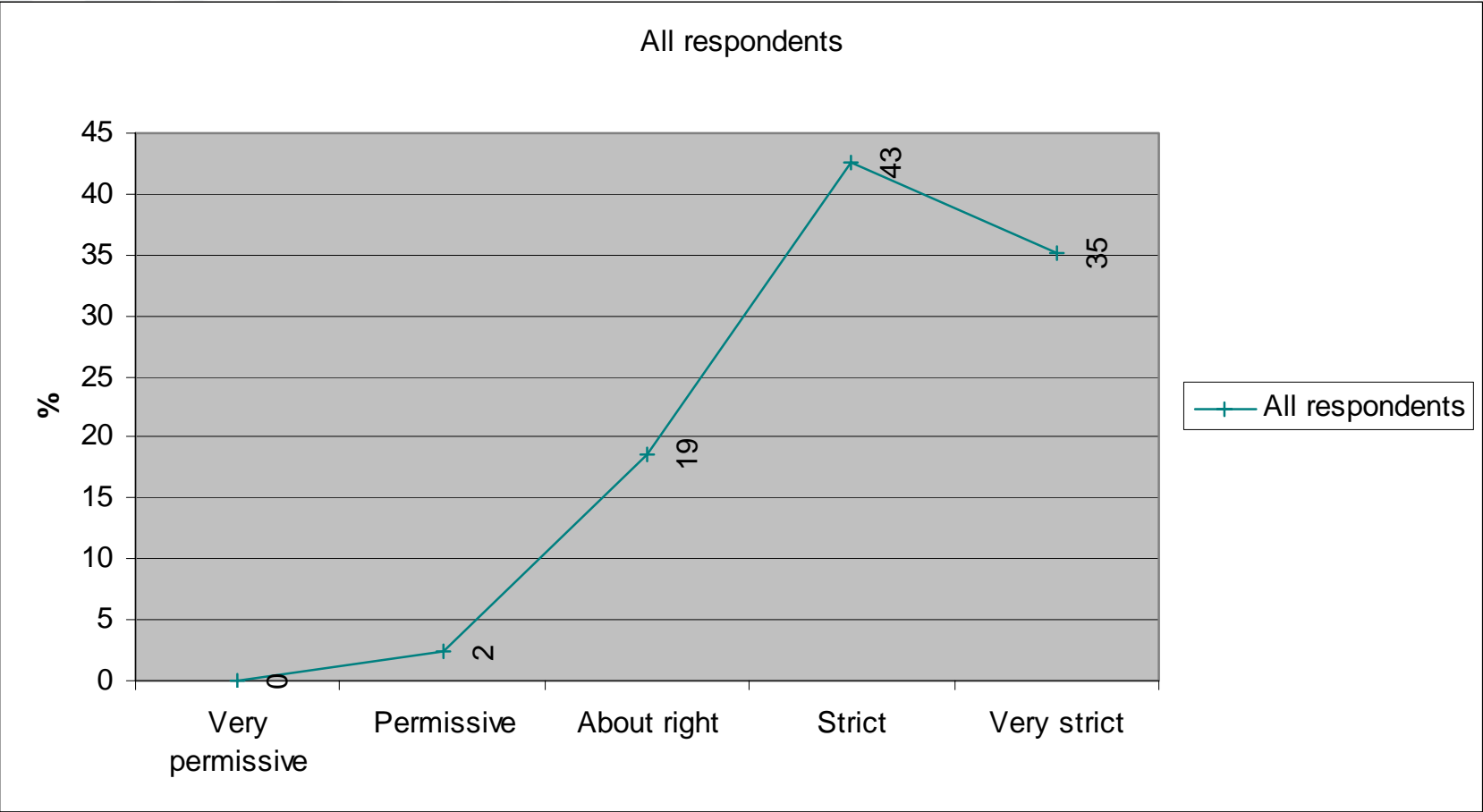
- 242 respondents.
- 73% described themselves as active in research using human tissue or biological samples.
- 61% percent of respondents were involved with pathology.

Consultant Pathologist	Trainee Pathologist	Clinical Scientist in Pathology	Biomedical Scientist	Scientific Researcher	Research Nurse	Tissue / Biobanker	Data Manager	Clinical Trialist	Other
112 (46%)	11 (5%)	16 (7%)	9 (3%)	59 (24%)	4 (2%)	44 (18%)	5 (2%)	58 (24%)	30 (12%)

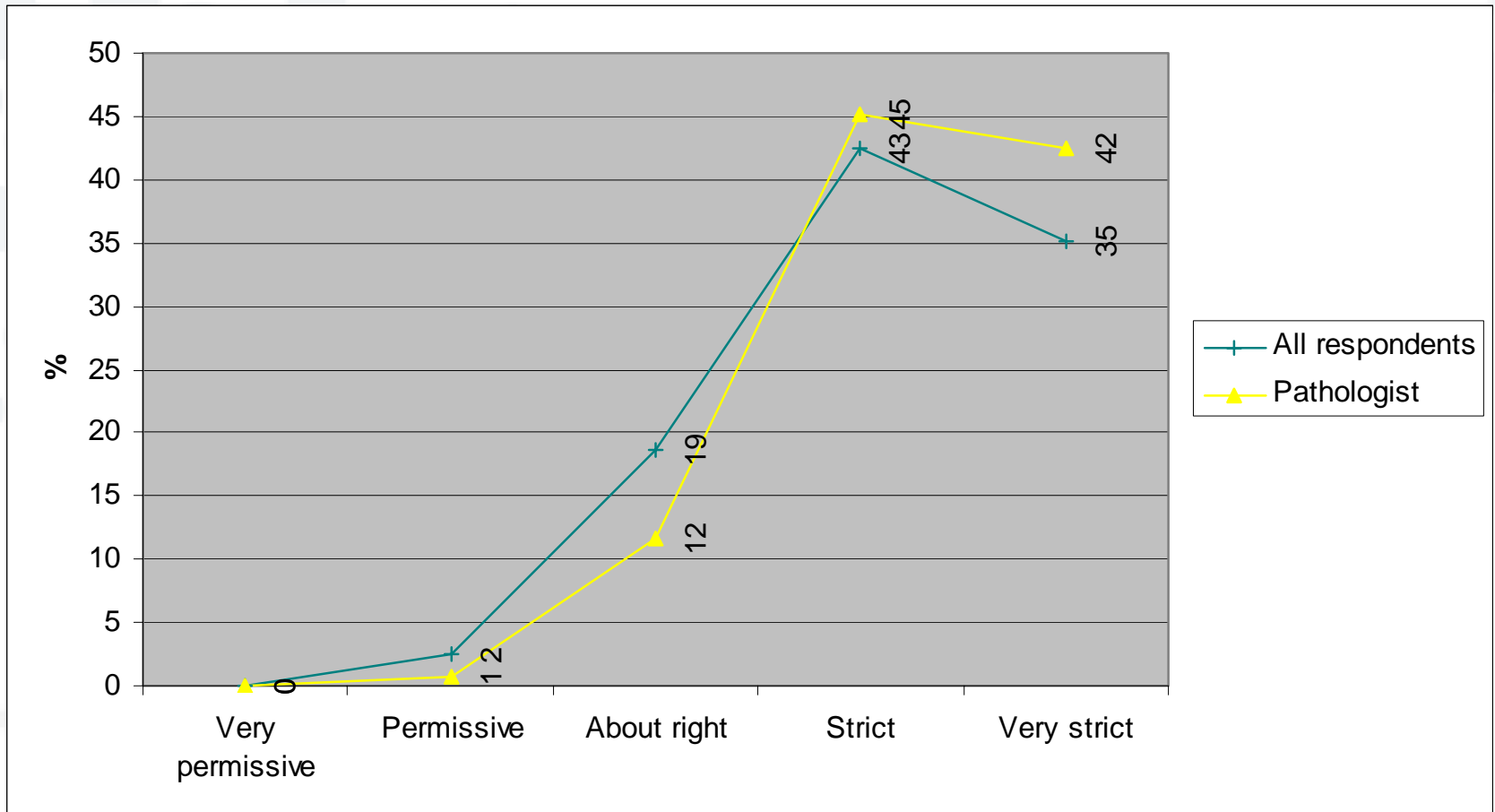
# Assessment of the regulatory and governance environment?

- How strict or otherwise is the regulatory and governance environment relating to research involving pathology?
- Do pathologists see it differently from others?

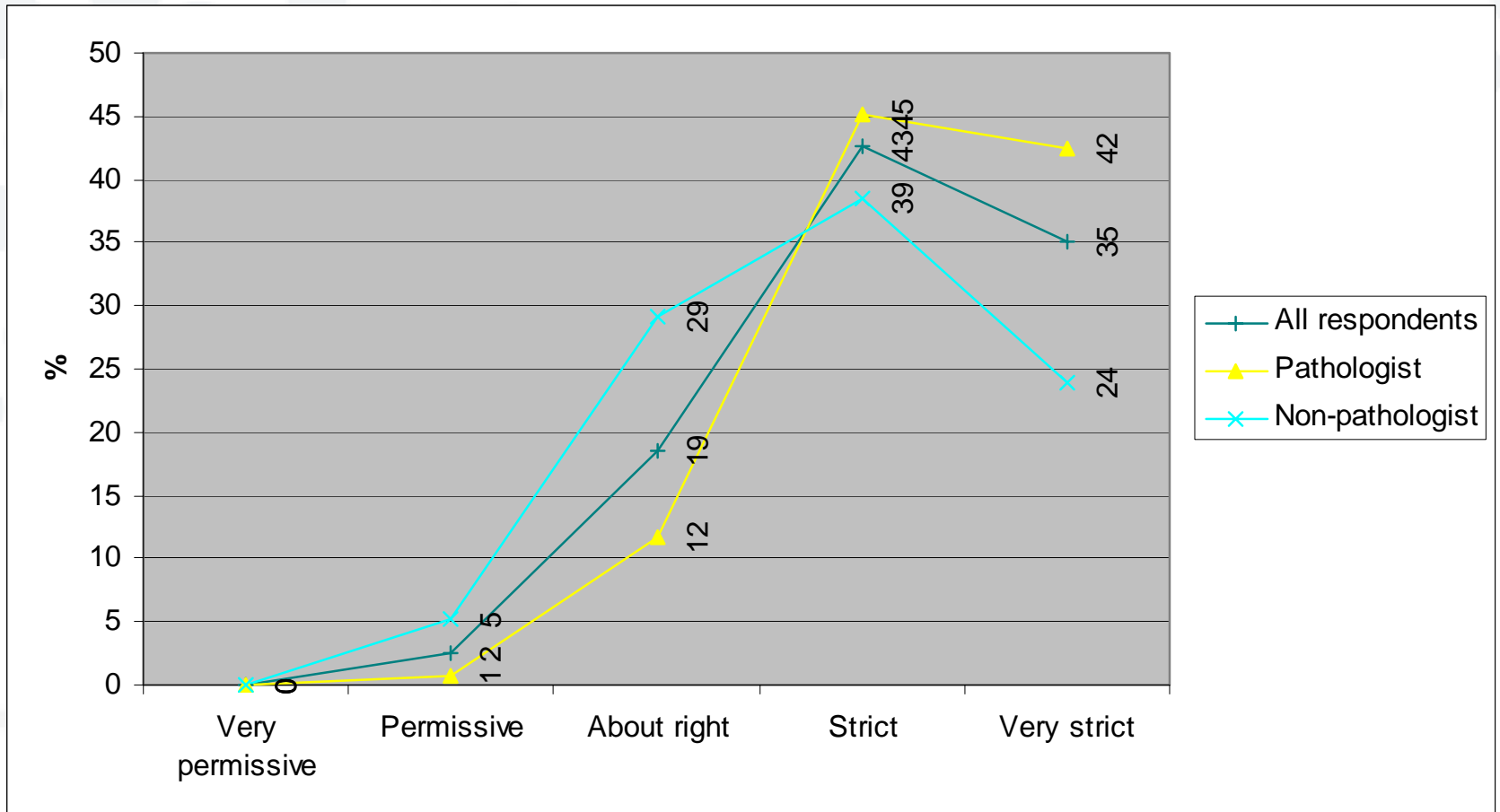
# Assessment of Regulatory & Governance Environment



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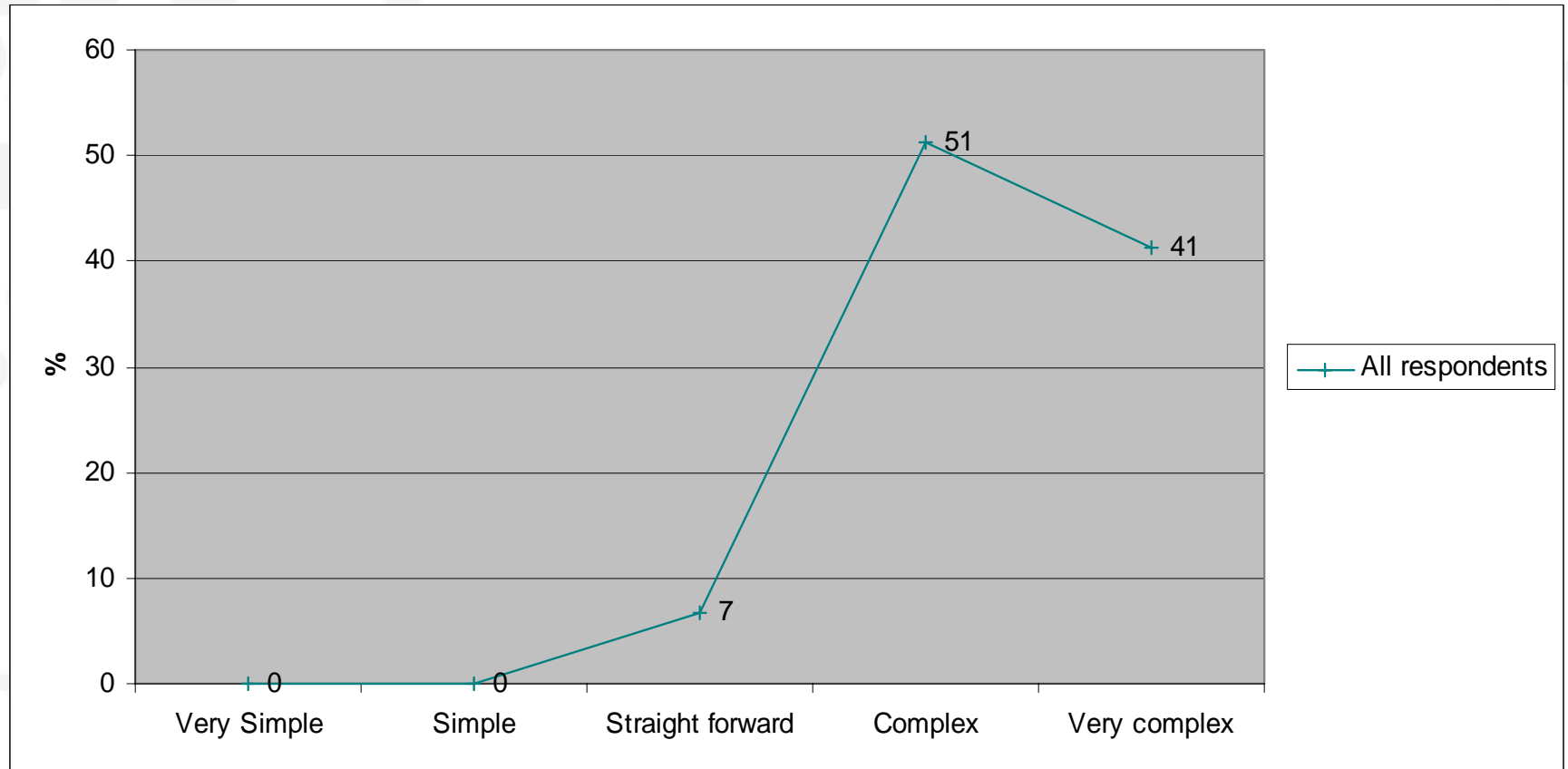
# Assessment of Regulatory & Governance Environment



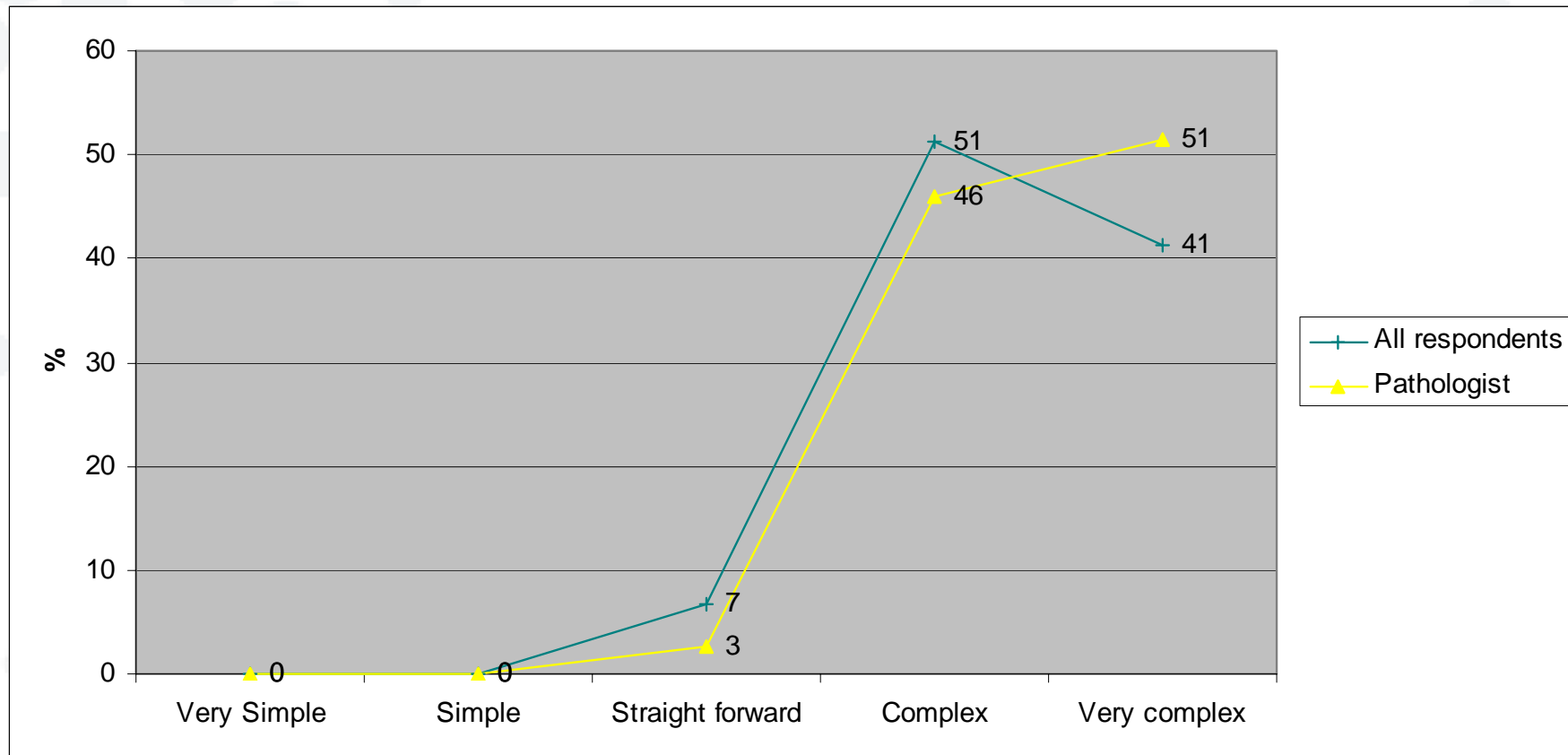
# Is strict synonymous with difficult or off-putting?

- Strict is only a problem if compliance is difficult to achieve:
  - Depends on complexity of regulatory and governance systems.
  - Willingness of users to work with these systems.
  - Fear of sanctions for non-compliance.

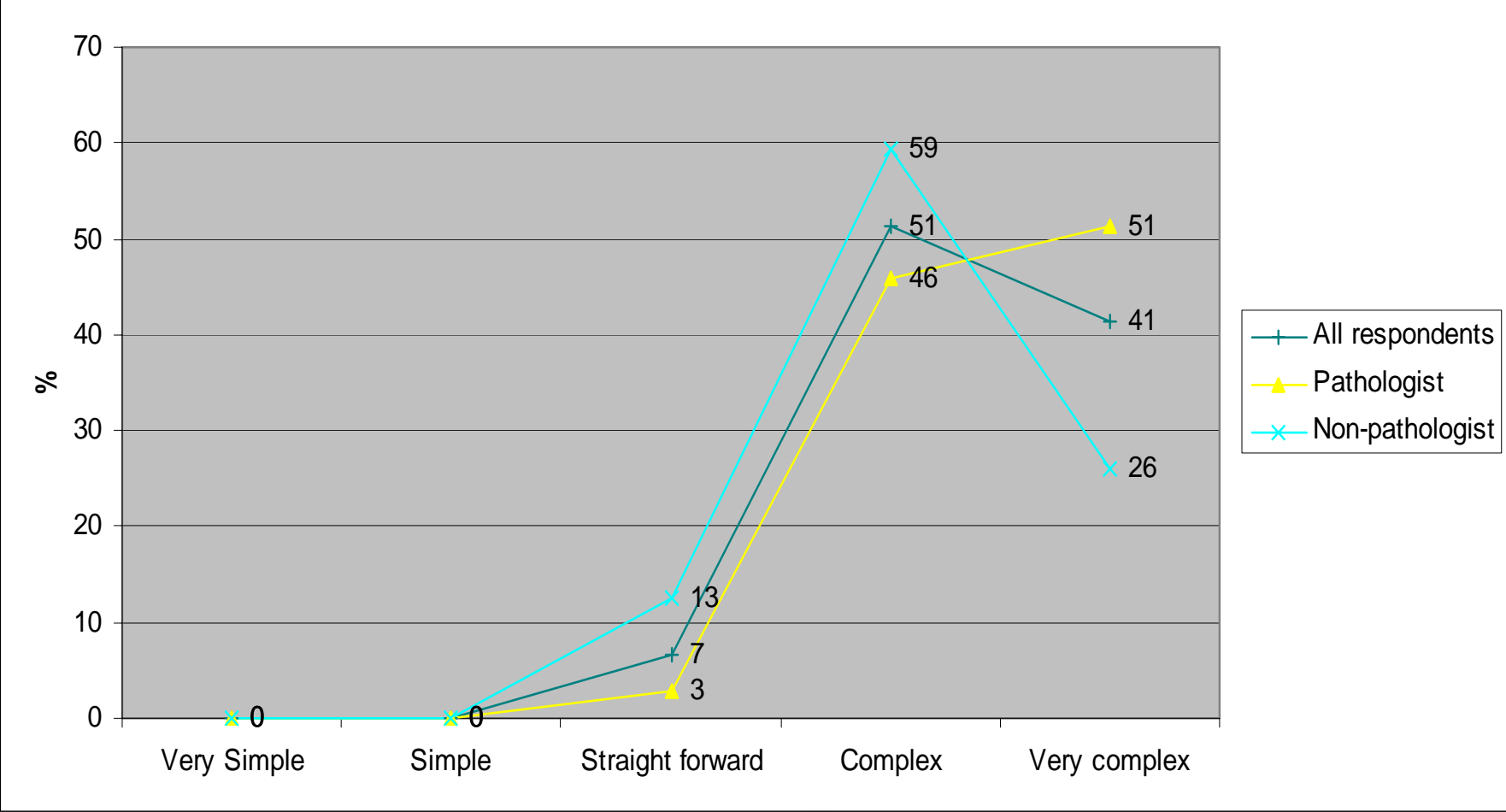
# Assessment of Complexity of Environment



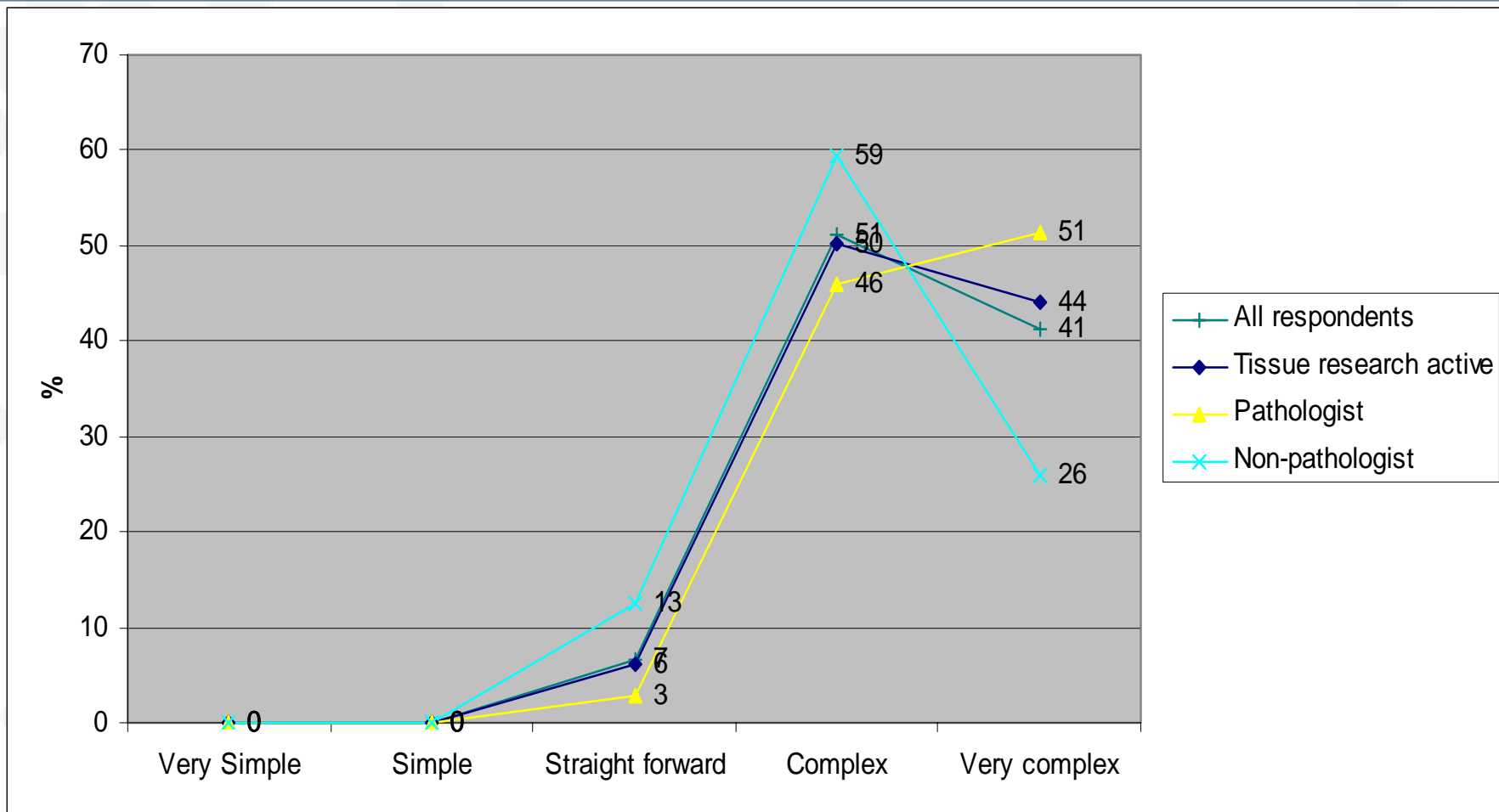
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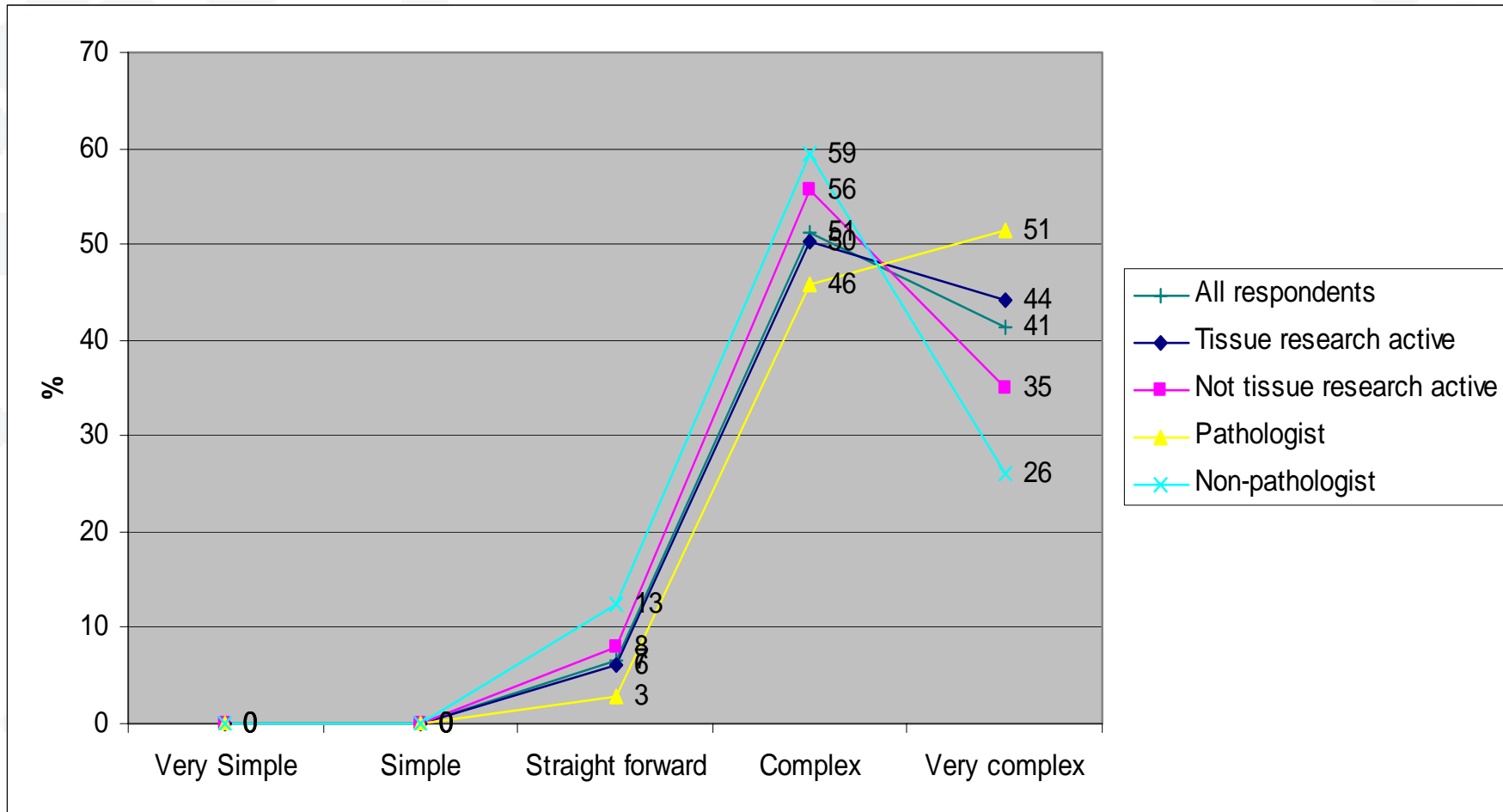
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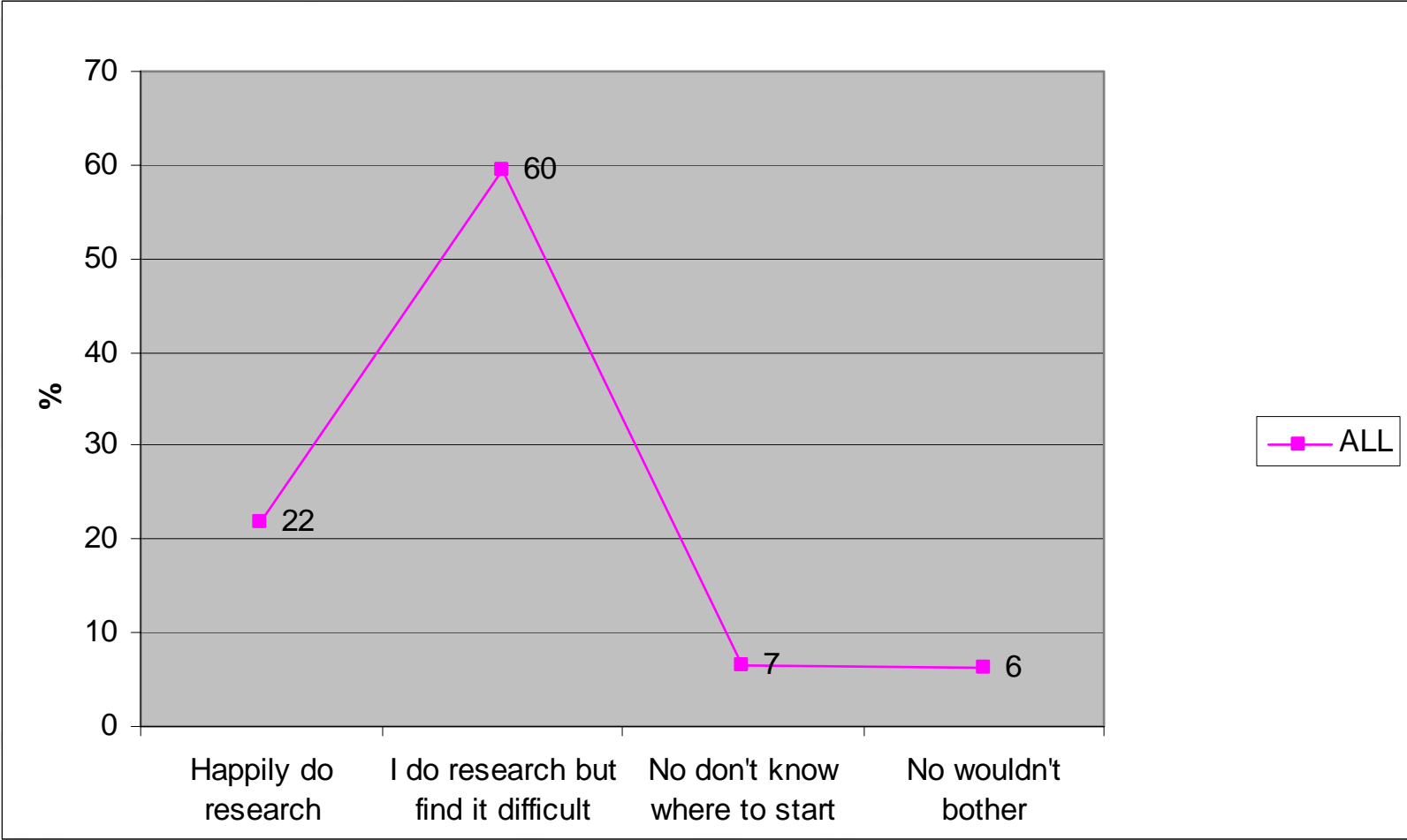
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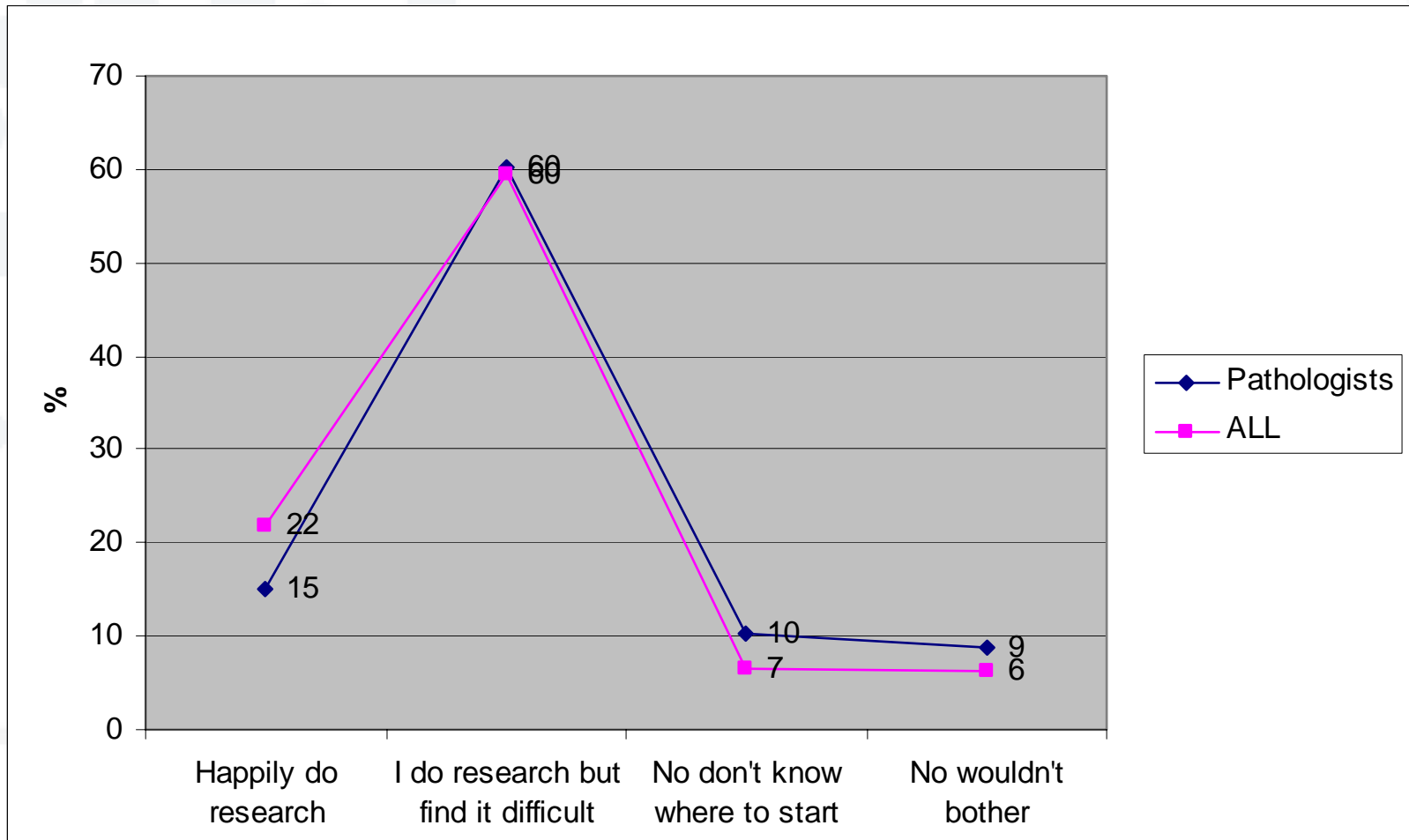
# What is the impact?

- So the regulatory and governance environment is perceived as strict and complex:
  - Particularly by pathologists – why?
  - Does it affect the willingness of pathologists to conduct, participate in or facilitate research?

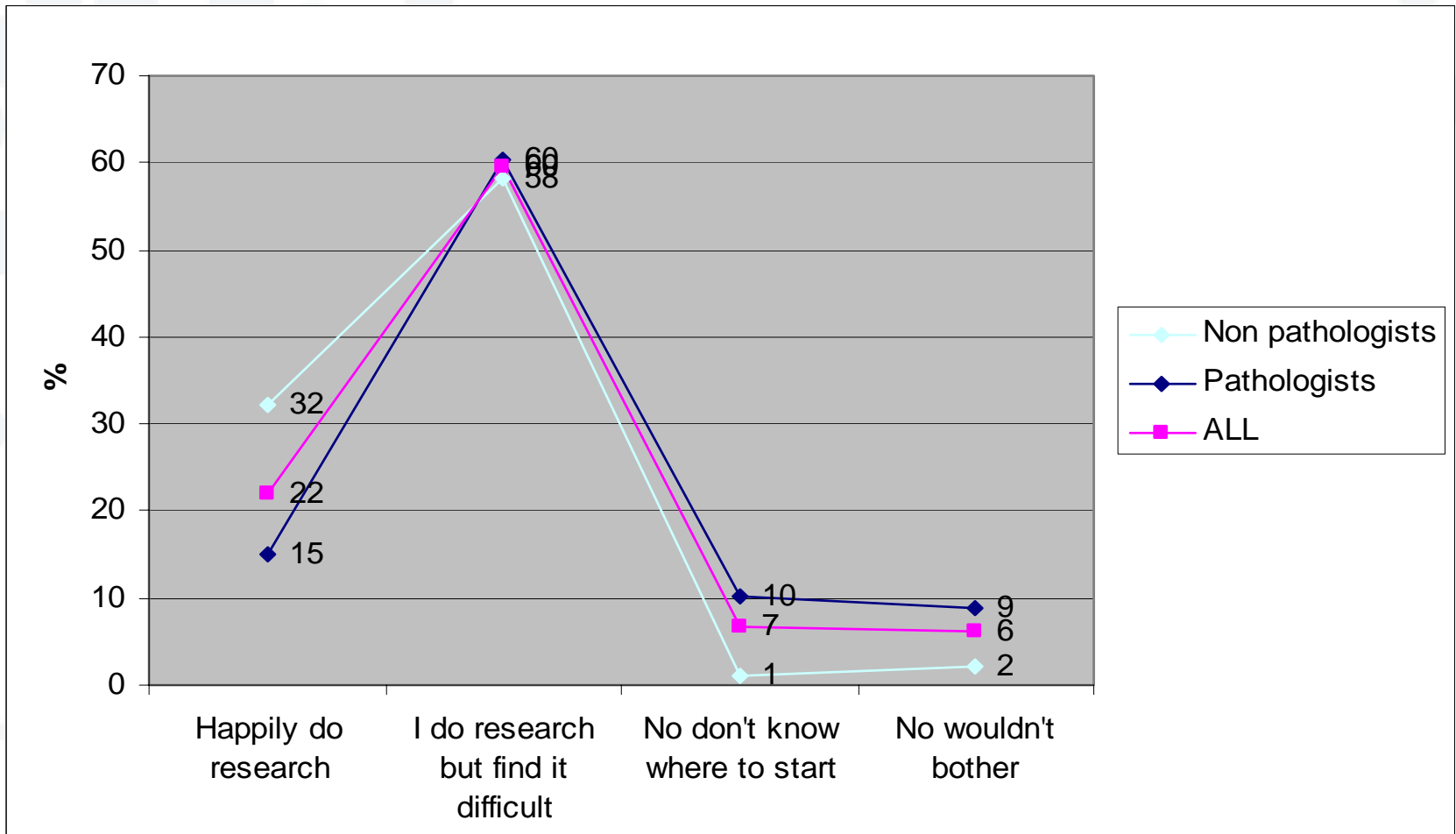
# Ability and willingness to do research



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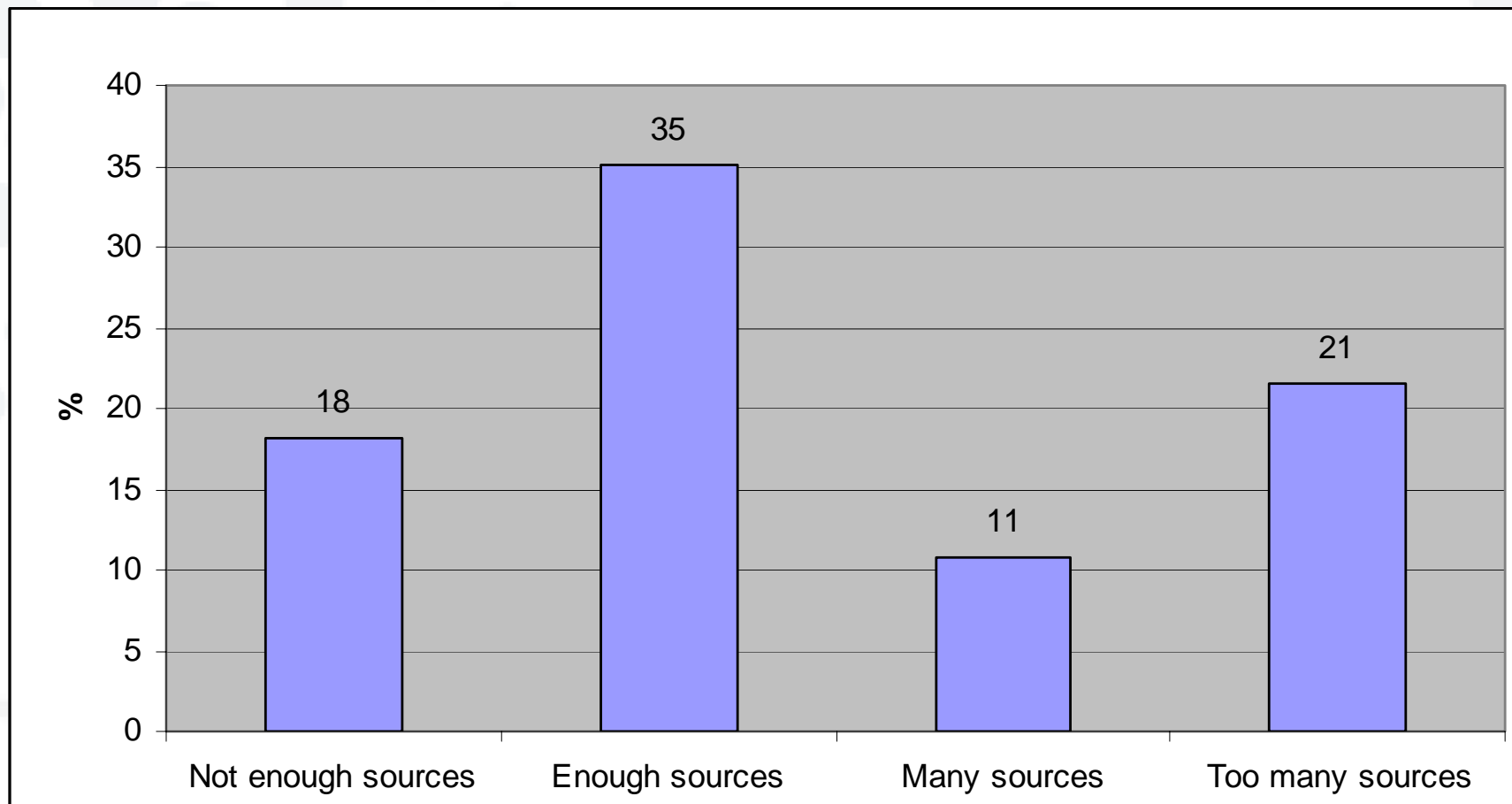
# Ability and willingness to do research



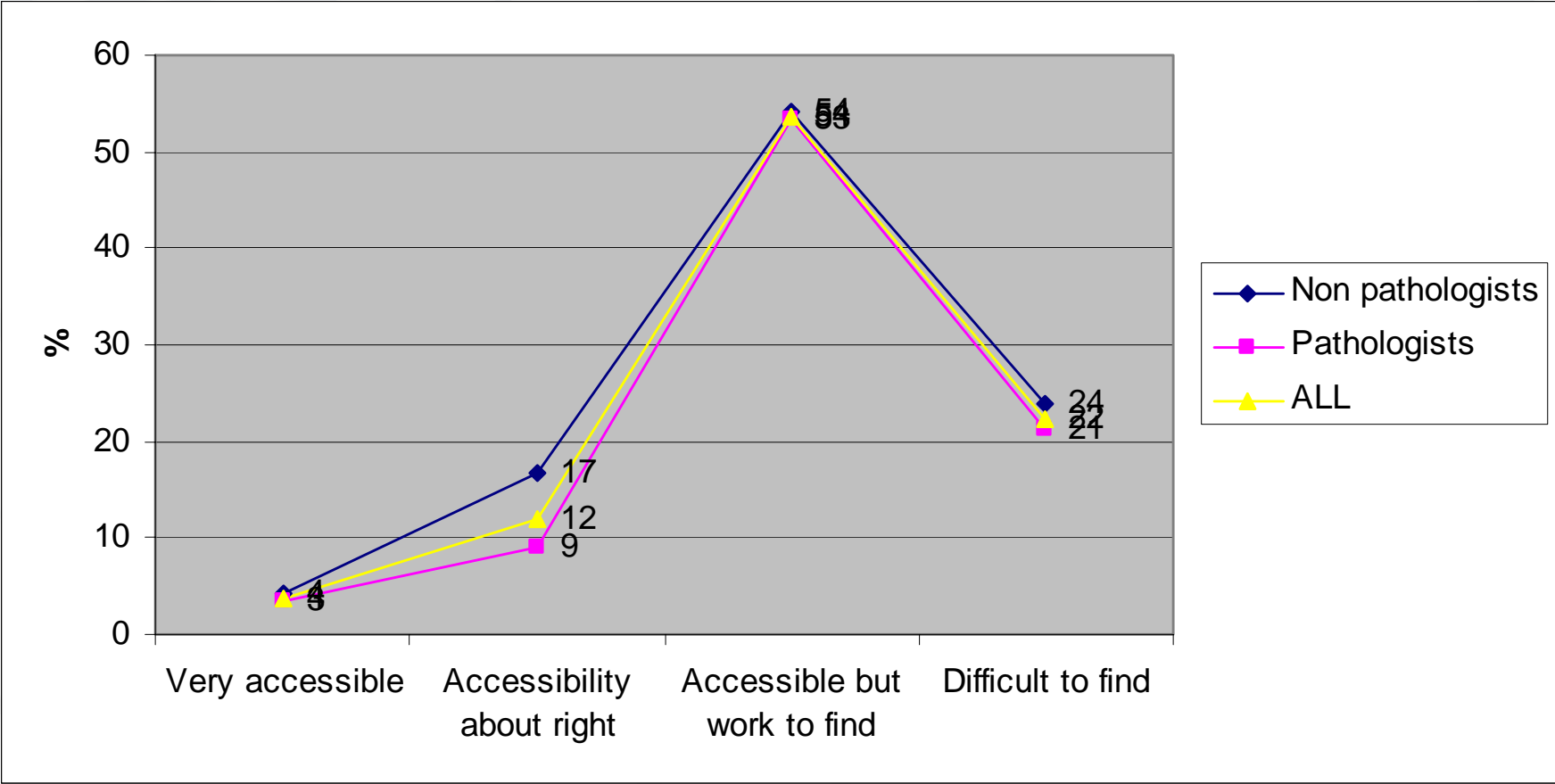
# Guidance – the antidote to complexity?

- Good clear guidance should make pathologists:
  - Less fearful of the perceived strictness.
  - More able to cope with the perceived complexity.
  - More likely to be research active?
- Is there a problem with the available guidance such that:
  - It hinders rather than helps?
  - It makes pathologists less likely to participate in research?

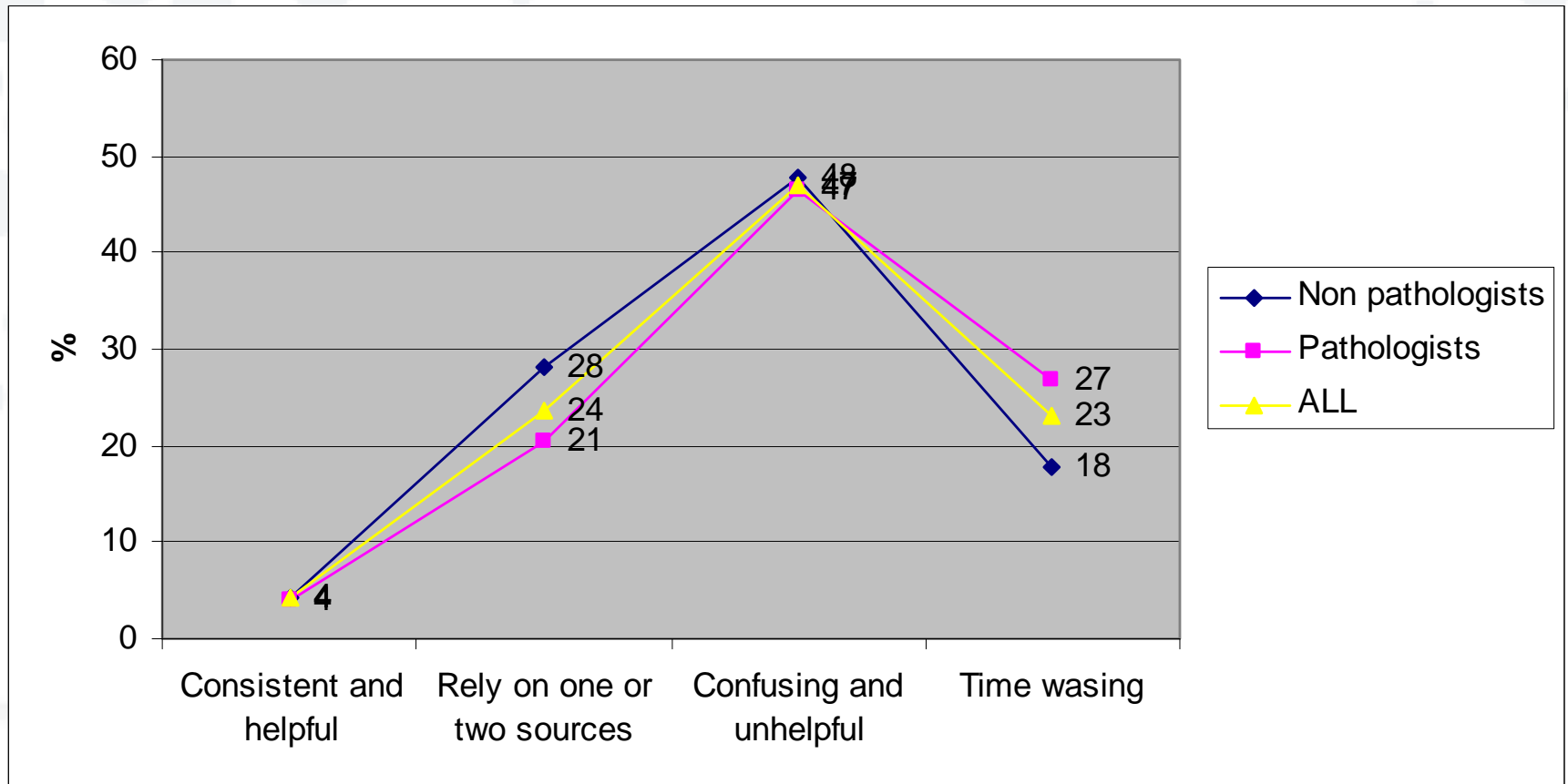
# Availability of Guidance - sources



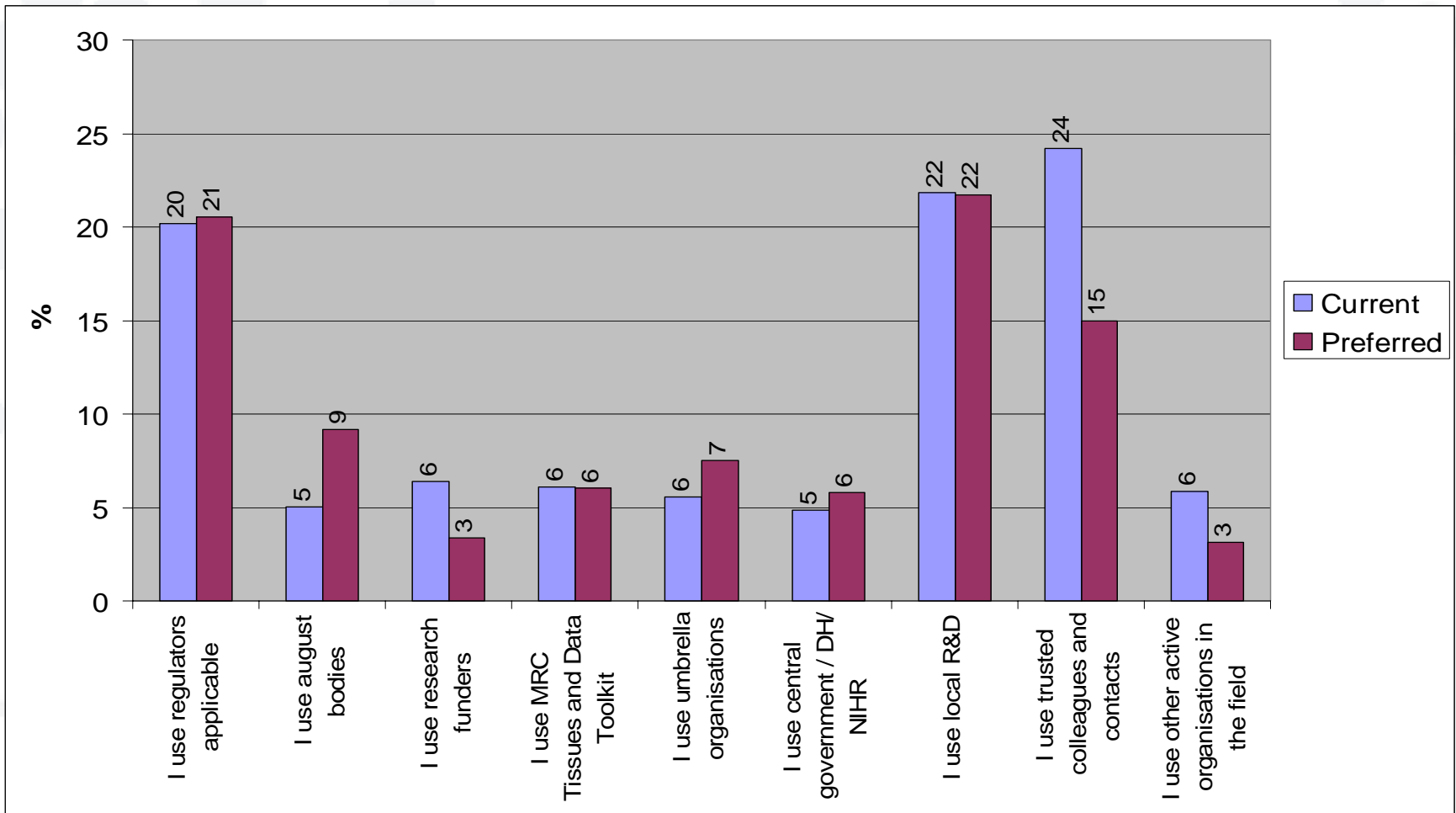
# Accessibility of Guidance



# Availability and Accessibility of Guidance – net effect



# Sources of Guidance – current and preferred



# Currently guidance isn't working!

- What should be done?
- Respondents were asked “if there was an easily accessible source of consolidated guidance endorsed by all regulators, would that make you more likely to be (more) research active?”
  - **83% (202) – yes.**
  - 13% (31) - no.
  - This pattern was repeated amongst all subgroups of respondents examined.

# The call for consolidated guidance

- “Emphatically yes, but it would need to be clear, up to date and easily accessible”
- “Yes, Yes, Yes and for goodness sake write it in simple language, and or provide human beings on the end of a phone who can talk one through it.”
- “This sounds like an excellent idea. Researchers require one place to go to be certain they are not contravening any regulations and that it should be simple to follow system that is not too time consuming. Although it must be rigorous so that peers and the public have confidence in the system.”

# Conclusions

- Current biomedical research extends across areas overseen by a wide variety of regulatory and governance bodies. Most researchers perceive several regulators as concurrently applicable to their work.
- The overall regulatory and governance environment is perceived as strict and complex, with a tendency to being seen as over strict and over complex.
- This is a particular problem for pathologists and for those actively working in human tissue or biological sample based research.

# Conclusions

- The willingness and ability of researchers to do their research is impaired as many find it difficult and some do not do research as a result.
- The provision of guidance is the best means of explaining the complex and strict regulatory and governance environment and enabling researchers to do their work in compliance with regulatory requirements. However, currently available guidance can be confusing, unhelpful and can lead researchers to waste time.
- Most respondents to this survey currently seek guidance from multiple distinct sources and would prefer to reduce this necessity.

# Recommendations

- **Recommendation 1** – Guidance should be consolidated into an accessible, authoritative and consistent multi-regulator endorsed resource.
- **Recommendation 2** – A consolidated guidance resource should be made available to researchers from a restricted number of regular sources, principally via the network of NHS Research and Development Offices and via the applicable regulators. These sources of the consolidated guidance resource can then be relied upon by researchers without recourse to check alternative sources.

# Acknowledgements

- I am indebted to the following for their various contributions to this survey and report:
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- I am also particularly grateful to the 242 individuals who participated in this survey by offering their completed questionnaires for analysis.