Health Innovation Wessex

Independent evaluation of iQAAPS

A digital tool to audit aseptic pharmacy services within Trusts and Health Boards in England and Wales

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Part of the Health Innovation Network

The evaluation team

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Disclaimer

The final report presents findings from an evaluation of iQAAPS conducted by Health Innovation Wessex (HIW). The findings of this evaluation are those of the authors and do not necessarily represent the views of QuiqSolutions Ltd or the Specialist Pharmacy Service.

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Abbreviations

HIW	Health Innovation Wessex
CQC	Care Quality Commission
GPhC	General Pharmaceutical Council
iQAAPS	interactive Quality Assurance of Aseptic Preparation Services
KPI	Key performance indicator
N/A	Not applicable
NE	North East
NW	North West
PAQ	Pre-audit Questionnaire
QA	Quality assurance
QAAPS	Quality Assurance of Aseptic Preparation Services
QI	Quality indicators
RPS	Royal Pharmaceutical Society
SE	South East
SPS	Specialist Pharmacy Service
SW	South West
WDL	Wholesale Dealer Licence
WTE	Whole time equivalent

Background

- The NHS Specialist Pharmacy Service (SPS) acts as an expert and informed body on unlicensed NHS pharmacy aseptic preparation. Offering guidance on best practice, they develop standards and carry out auditing services as per Department of Health Executive Letter, EL(97)52, for services who prepare and manufacture medicines. SPS quality assurance (QA) officers undertake the audits and reports. There have been concerns about the transparency of the results of these audits and the lack of understanding at NHS trust board level of the board's responsibility and accountability, particularly the importance of implementing required remedial actions and the need to prioritise associated works.[1]

- The recent national report titled 'Transforming NHS pharmacy aseptic services in England' by Lord Carter of Coles recommended strengthening the accountability and responsibility around the unlicensed preparation of aseptic medicines under EL(97)52 guidance and the role of the Chief Pharmacists.

- In October 2021, QuiqSolutions (https://www.quiqsolutions.com) was commissioned by the SPS to provide a digital tool for managing the auditing of Aseptic Pharmacy Services within trusts and health boards across the United Kingdom. The Quality Assurance of Aseptic Preparation Services (QAAPS) standards have been operationalised onto a bespoke web-based digital system ('iQAAPS') for audit and oversight of unlicensed NHS Pharmacy Aseptic Units.

- In April 2023, iQAAPS became a mandatory part of NHS England national guidance for the aseptic preparation of medicines.[1]

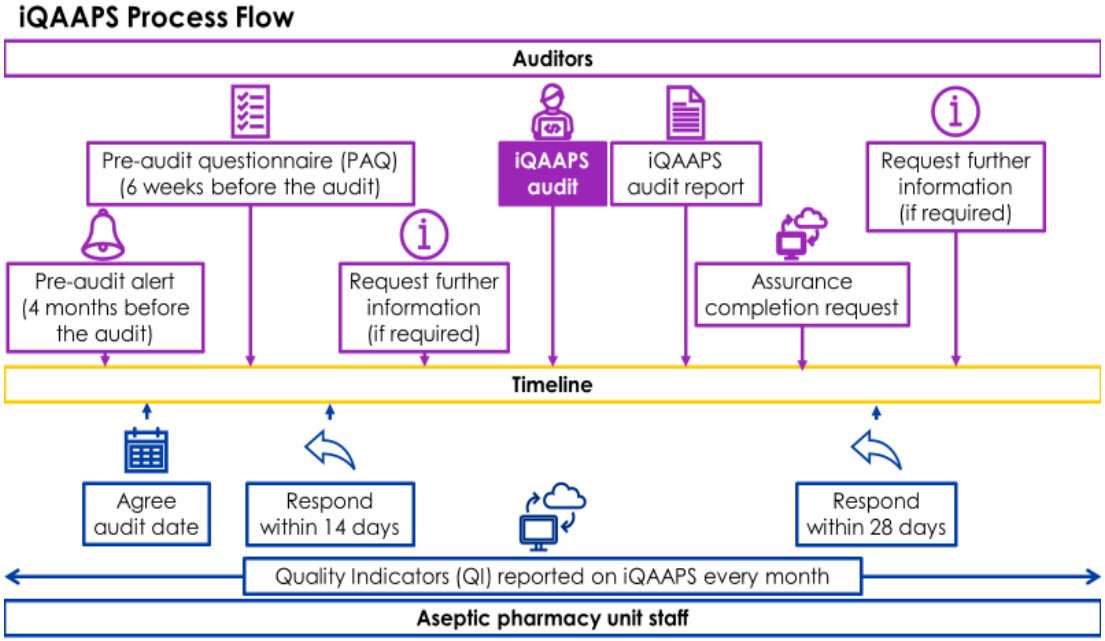
- Several benefits of the iQAAPS digital platform are anticipated - that it will drive consistency across audits, provide a way to capture data across many services, be a way to compare performance of many services, identify common deficiencies, be a vehicle for quality improvement at the services who prepare and manufacture medicines, and raise the general awareness of quality assurance.

- It should be noted that prior to implementation of iQAAPS there was regional and unit level variation in elements of the audit process. For example, some units may not have been previously required to complete a Pre Audit Questionnaire (PAQ), the information requested as part of the PAQ document varied between units in different regions, the previous audit report was free-typed and therefore had significant variation in style and content between auditors and regions. Also, action plans were developed locally in a variety of formats by unit management teams and held on local systems. Given the different starting points for each unit, regional disparity in the perceived value and impact of iQAAPS is likely.

1. https://www.england.nhs.uk/long-read/assurance-of-aseptic-preparation-of-medicines/

Background

- Key regulatory guidance for aseptic dispensing in NHS hospitals was the 1997 NHS Executive letter EL(97)52.
- In April 2023, the EL(97)52 guidance was replaced by the NHS England national guidance for the aseptic preparation of medicines: https://www.england.nhs.uk/long-read/assurance-of-aseptic-preparation-of-medicines/
- A typical audit involves a range of activities over many months.
- Key stakeholders in the audit process are the Accountable Pharmacist (Unit staff), Chief Pharmacist of the NHS trust the unit(s) resides within, and the auditor.



Evaluation questions

The evaluation questions were developed with several stakeholders prior to starting the study.

1. What is the perceived acceptability of iQAAPS by key stakeholders? (Auditors, unit staff, Chief Pharmacists)

2. What has helped and hindered the implementation of iQAAPS?

3. Do iQAAPS-supported audits provide oversight of governance and assurance arrangements in the aseptic units?

4. What is the impact of iQAAPS-supported audits on quality assurance processes?

5. What is the impact of iQAAPS-supported audit action plans on improving compliance at manufacturing units?

6. Do iQAAPS-supported audits result in wider impacts for stakeholders? (e.g. financial, personnel, hospital processes, governance, educational impacts)

7. Do you think iQAAPS could be used to audit compliance in any other areas (e.g. medical gases)?

8. What improvements could be made to iQAAPS to support effective quality assurance?

Evaluation methodology

The evaluation took place between December 2022 and September 2023.

The evaluation took a multi-perspective approach and used a mixed methods survey design with nested qualitative case studies to answer the evaluation questions.

1. Survey 1: Accountable Pharmacists (unit staff).

2. Survey 2: Chief Pharmacists.

3. Survey 3: Auditors.

4. Case studies of high-risk units – focused on services categorised by SPS auditor 'at high-risk' / failing to meet the necessary standards to understand how iQAAPS has been used to respond to the audit findings. Where possible, one-hour interviews were conducted separately with the Chief Pharmacist, Accountable Pharmacist, and auditor for each case study. Thematic analysis was used to develop the findings.

Staff were recruited if they had been involved in an iQAAPS audit in England or Wales. Data collection was supported by the Specialist Pharmacy Service.

All surveys focused on perceptions of value, training, the pre-audit phase, the audit phase, the audit outputs, and impacts of iQAAPS.

Synthesised survey responses

Responses from the Unit Staff, Chief Pharmacist, and Auditor Surveys are brought together under these themed areas:

1. Survey respondents
2. Perceptions of overall value of iQAAPS
3. Training, Pre-Audit Questionnaire, System access
4. The audit process
5. The audit outputs
6. Impact of iQAAPS

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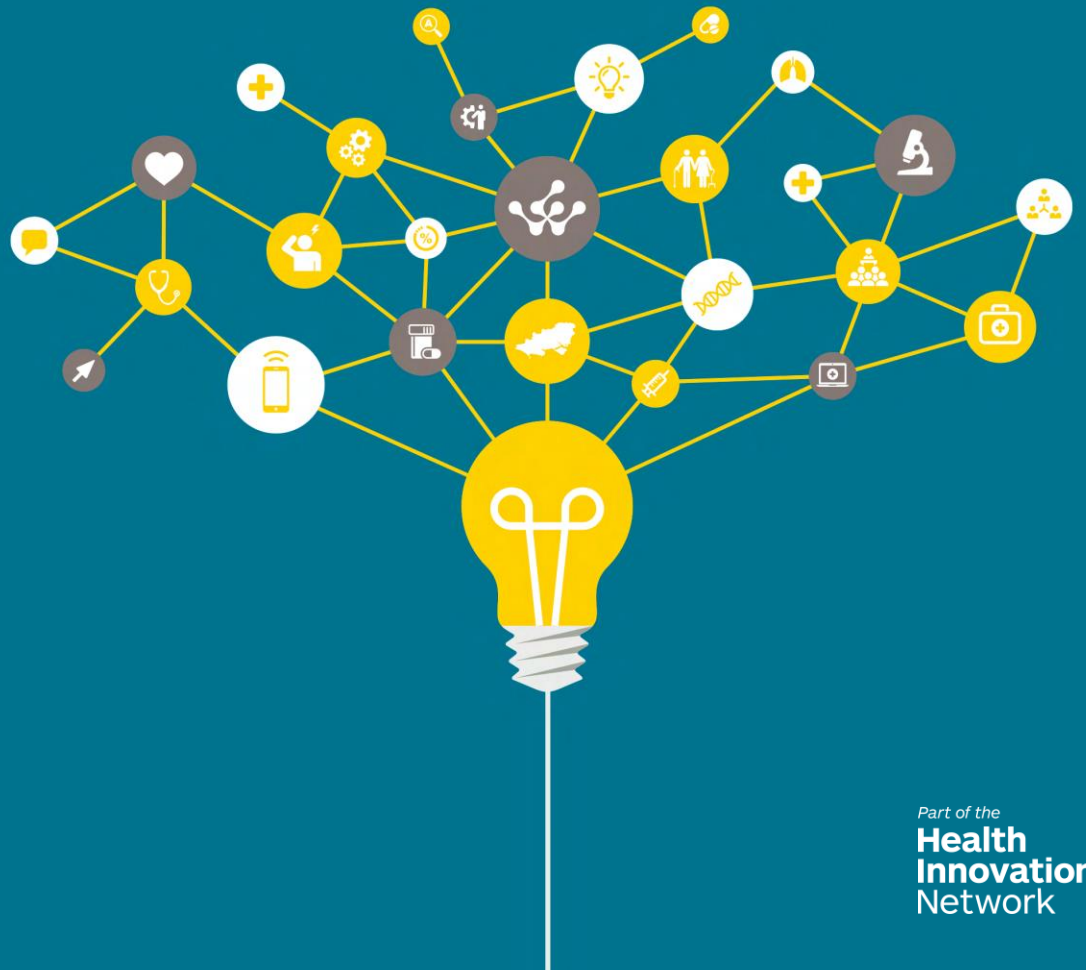
Survey respondents



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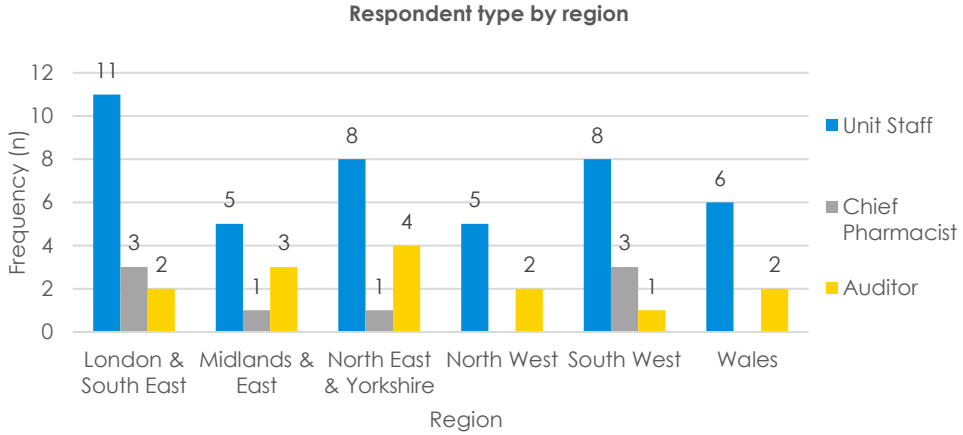
Survey respondents

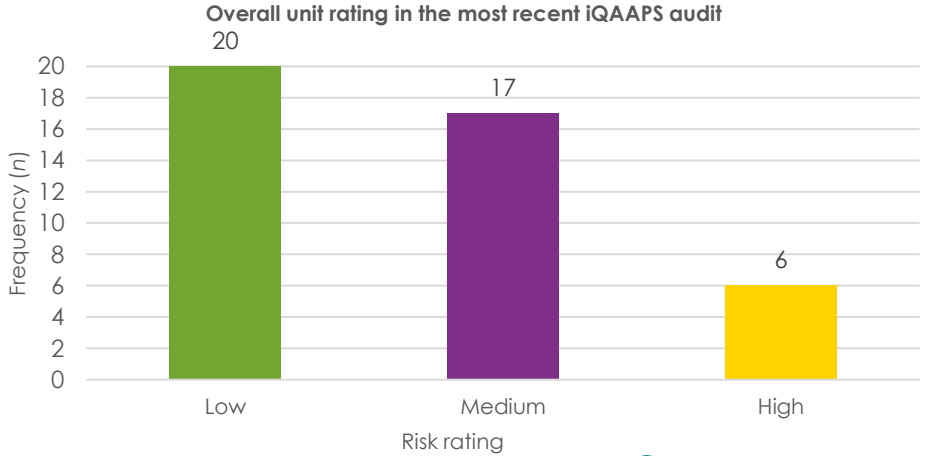
65 responses in total were received across the three surveys.

43 Unit Staff Survey responses were received (**62% response rate** of units that had conducted an audit with iQAAPS), of which 46.5% (*n*=20) were linked to low-risk units, 39.5% (*n*=17) linked to medium-risk units, and 14.0% (*n*=6) linked to high-risk units.

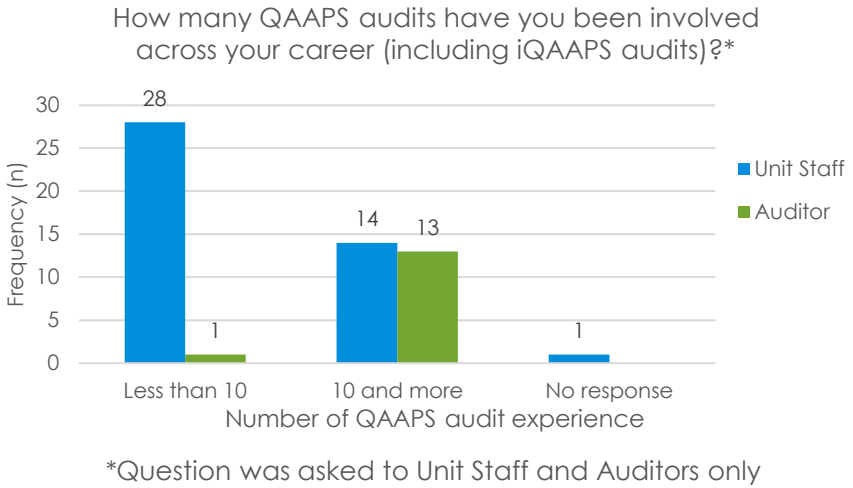
8 Chief Pharmacist Survey responses were received (**13% response rate** of Chief Pharmacists overseeing units that had conducted an audit with iQAAPS).

14 Auditor Survey responses were received (**70% response rate** of auditors who had conducted an audit with iQAAPS).

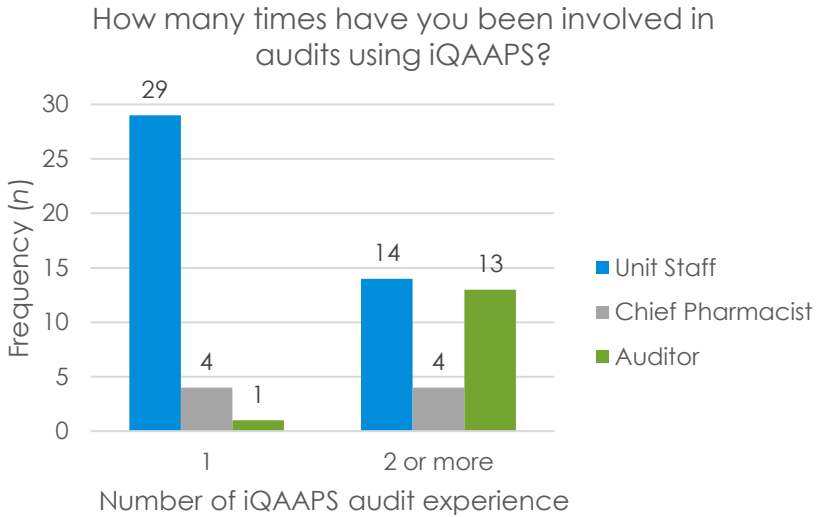




Survey respondents

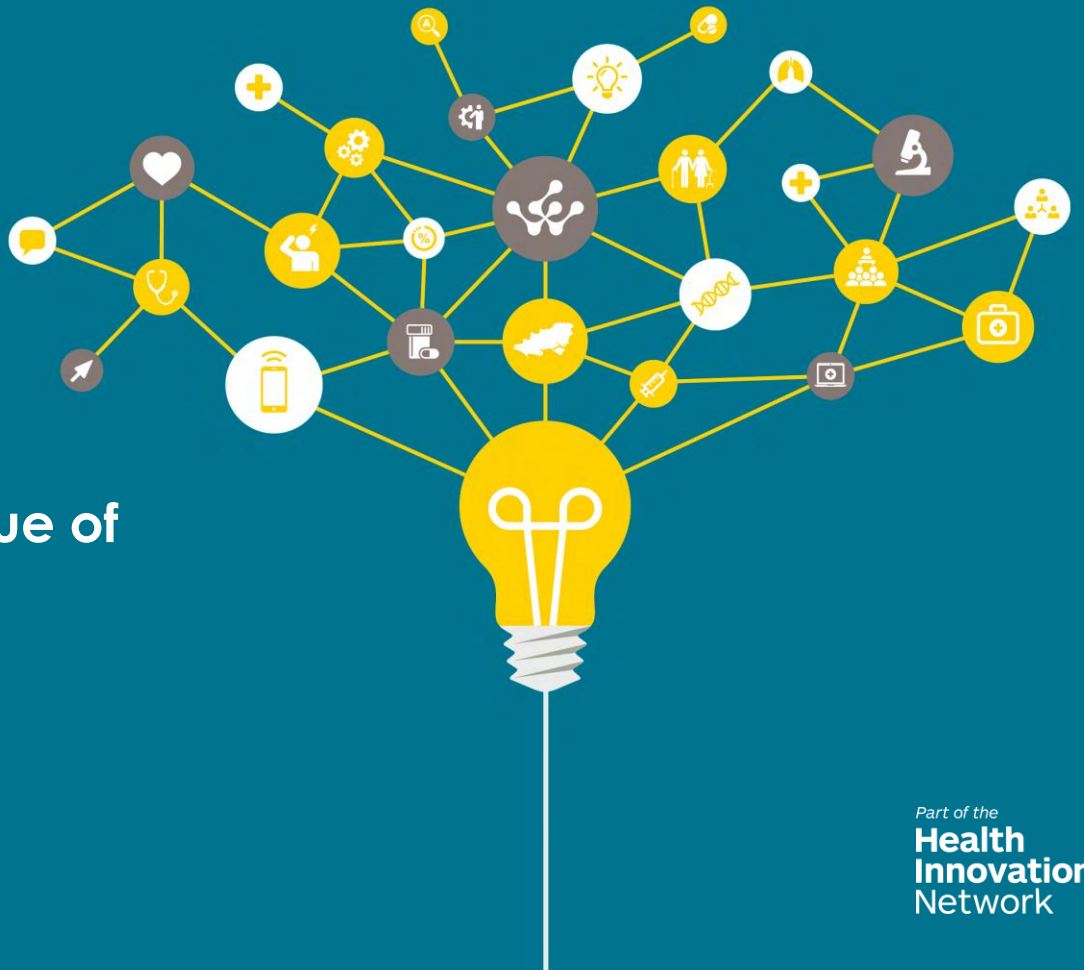


*Question was asked to Unit Staff and Auditors only



- The survey respondent findings indicate most respondents were linked to units with low or medium risk ratings.
- Unit staff had various levels of experience with QAAPS audits and iQAAPS specifically.
- Two-thirds of unit staff had only used iQAAPS once.
- Views about iQAAPS were obtained across the regions.

Perceptions of overall value of iQAAPS



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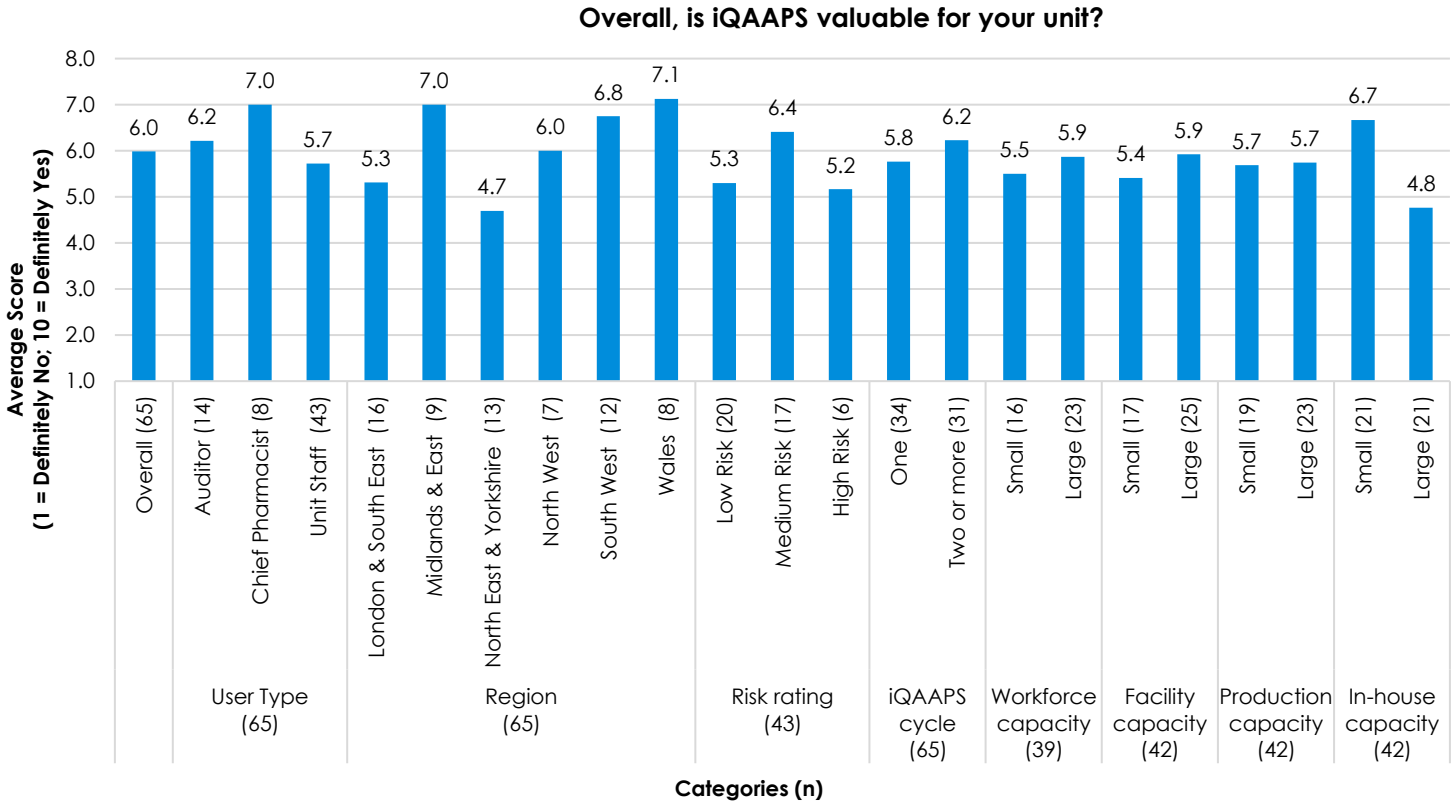
Perceptions of overall value – whole sample and subgroups



- When considering iQAAPS as a complete package, respondents reported a moderate level of acceptability (mean score 6.0).
- Wide variation in views exist and are influenced by the role and context of the respondent.
- See Appendix B for capacity definitions

Acceptability of iQAAPS

- Chief Pharmacists were the most positive toward iQAAPS, followed by the auditors, and then individual unit staff.

Chief Pharmacists:

- "It's factual, with audit outcomes set against the specific standards, rather than a very long written account that for chief pharmacists is hard to understand real areas of risk or concern…[iQAAPS] gives a clear yes or no where standards have been assessed and a clear indication where they have not been assessed and it's much easier to understand good and bad performance."
- "[iQAAPS] allows me to see progress all the time and use it as a tool to maintain quality within the unit and between audits."
- "It's a consistent, permanent record, that is automated and standardised."
- "It's a good step in the right direction but needs some refining to be more user friendly."

Auditors:

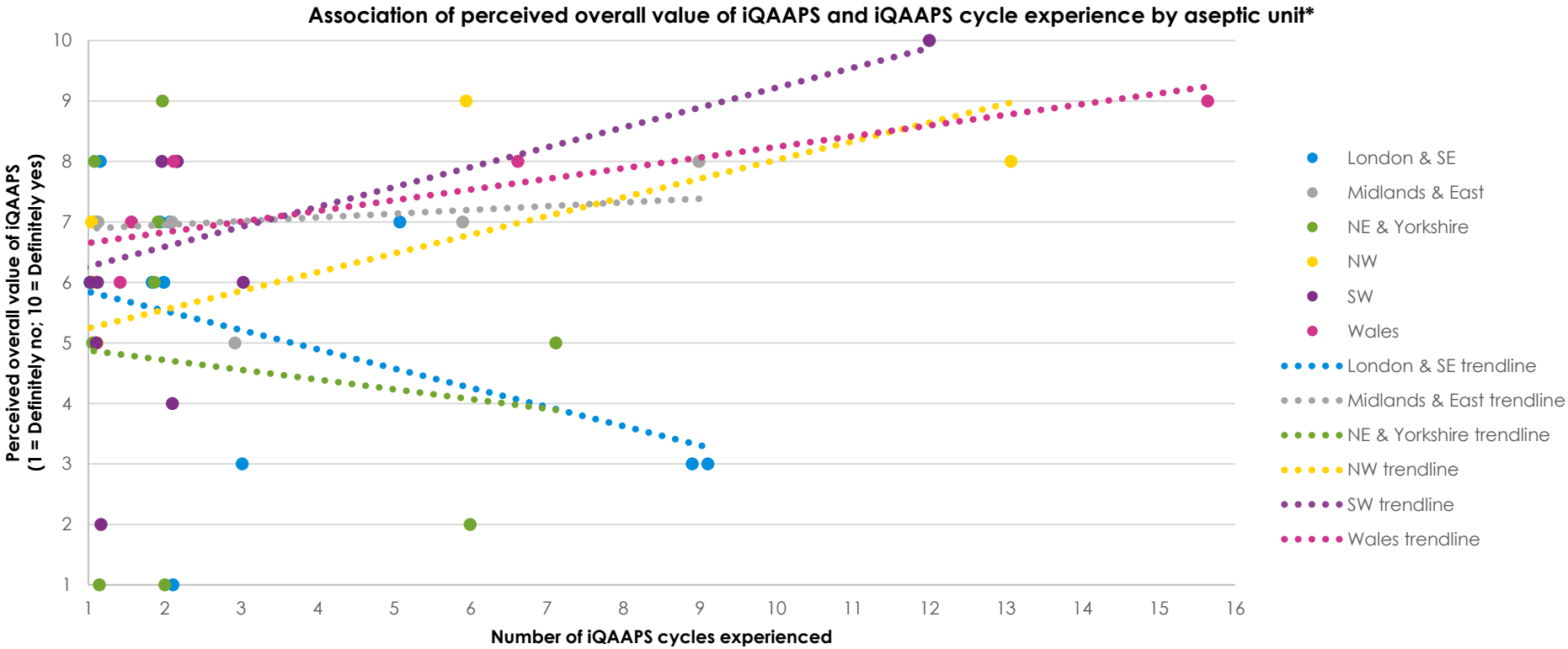
- "iQAAPS makes the overall picture of standards of aseptic units across the country clearer, with better comparisons between units, and improves the quality of monitoring of unit performance."
- "It is good that all the auditors are using a common system with the same set of documents collected as part of the Pre-Audit Questionnaire. This should improve consistency."
- "iQAAPS encourages more involvement from Chief Pharmacists in the process."
- "iQAAPS provides clarity on the audit outcome and visibility of the progress of action plans."
- "iQAAPS allows me to complete more preparation before going on site to aid the actual audit process…I'm able to target areas already identified as possible issues."

Acceptability of iQAAPS

Mixed levels of acceptability were reported from Accountable Pharmacists (Unit Staff):

- Positive: "I really like the system. I think once you get used to how it works it is a massive improvement. It helps with closing out actions and I like the alignment for everyone and the oversight it offers to the Chief Pharmacist, quality assurance colleagues at region level, and the Specialist Pharmacy Service. I feel it is a supportive move forward for Accountable Pharmacists."
- Positive: "Comprehensive and consistent approach to audit."
- Positive: "I like that the auditor can only link to actual standards rather than comment on random points."
- Concerns: "I can see the potential but at present it is too challenging to manage."
- Concerns: "I like the idea of it. Unfortunately, it is slow and creates a lot more work."
- Concerns: "The action planning section needs work. It was necessary to create a separate action plan in Excel so we can provide trust-level assurance and updates. I would prefer an integrated action section so an action can be added within the ongoing review that can then be extracted as a whole action plan for sharing."
- Concerns: "Difficult to navigate the site, I cannot export data into an easy-to-use format. The last time all the exported RAG ratings were wrong (in terms of colour). It is time consuming when a simple excel spreadsheet could be more user friendly. I cannot assign actions to appropriate staff as not enough user access and there are no trigger reminders received when actions are due review or completion. There are no trigger reminder when auditors have responded to action plan and I cannot view actions once signed off. I cannot tell when another owner has completed their actions."

Acceptability of iQAAPS



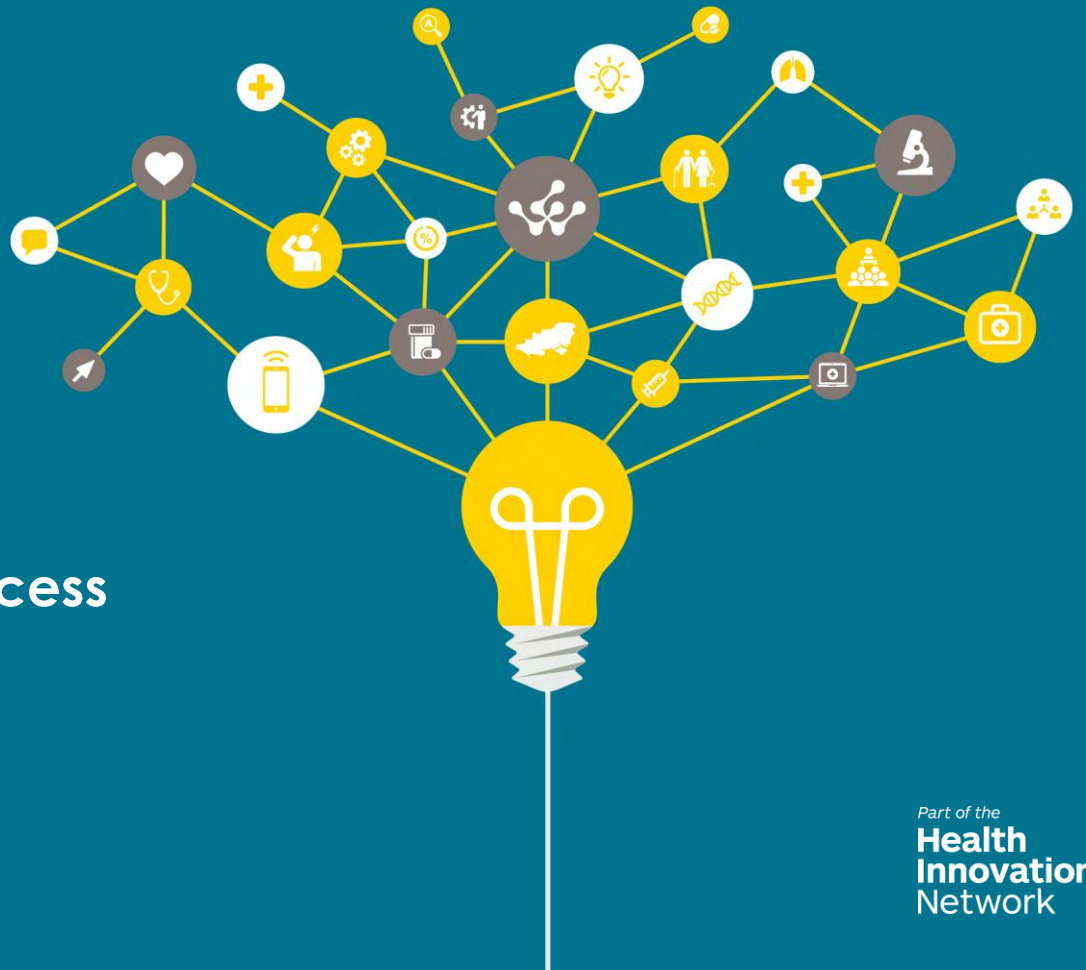
*Note: Data points are 'jittered' in this scatter plot to visualize the distribution of overlapping data points.

Abbreviations: NE = North East; NW = North West; SE = South East; SW = South West.

Section Summary: Perceptions of overall value

- iQAAPS was perceived to have adequate value when combining all stakeholder perceptions.
- Chief Pharmacists and auditors largely commented on the value of iQAAPS for oversight, transparency, and increased audit quality. Unit staff largely commented on the process of using iQAAPS and considered this more burdensome than previous audit support methods.
- Considerable variation in views about the value of iQAAPS was identified:
    - Chief Pharmacists valued iQAAPS more highly than auditors and, in particular, unit staff.
    - Wales, Midlands & East, and South West units valued iQAAPS more highly than other regions.
    - Units with a medium risk status valued iQAAPS more highly than units with either a low or high-risk status, suggesting units with very limited (low-risk) and very numerous (high-risk) post-audit actions have different experiences. It is possible high-risks sites have not only an increased workload but also an increased need to manage various operational challenges highlighted later in this report.
    - The level of experience users had with iQAAPS could positively or negatively affect their acceptability of iQAAPS. The overall perceived value of iQAAPS increased for some units/regions (e.g. Wales, South West, North West regions) after more experience was obtained but decreased for other units/regions.
    - Minimal differences were found between units with different levels of workforce, facility, and production capacity (see Appendix B for definitions). However, units with small levels of in-house capacity (percentage of production under Section 10 and Manufacturer's Specials (MS) licence against the unit's total production) reported more overall value of iQAAPS.

Training, Pre-Audit Questionnaire, system access



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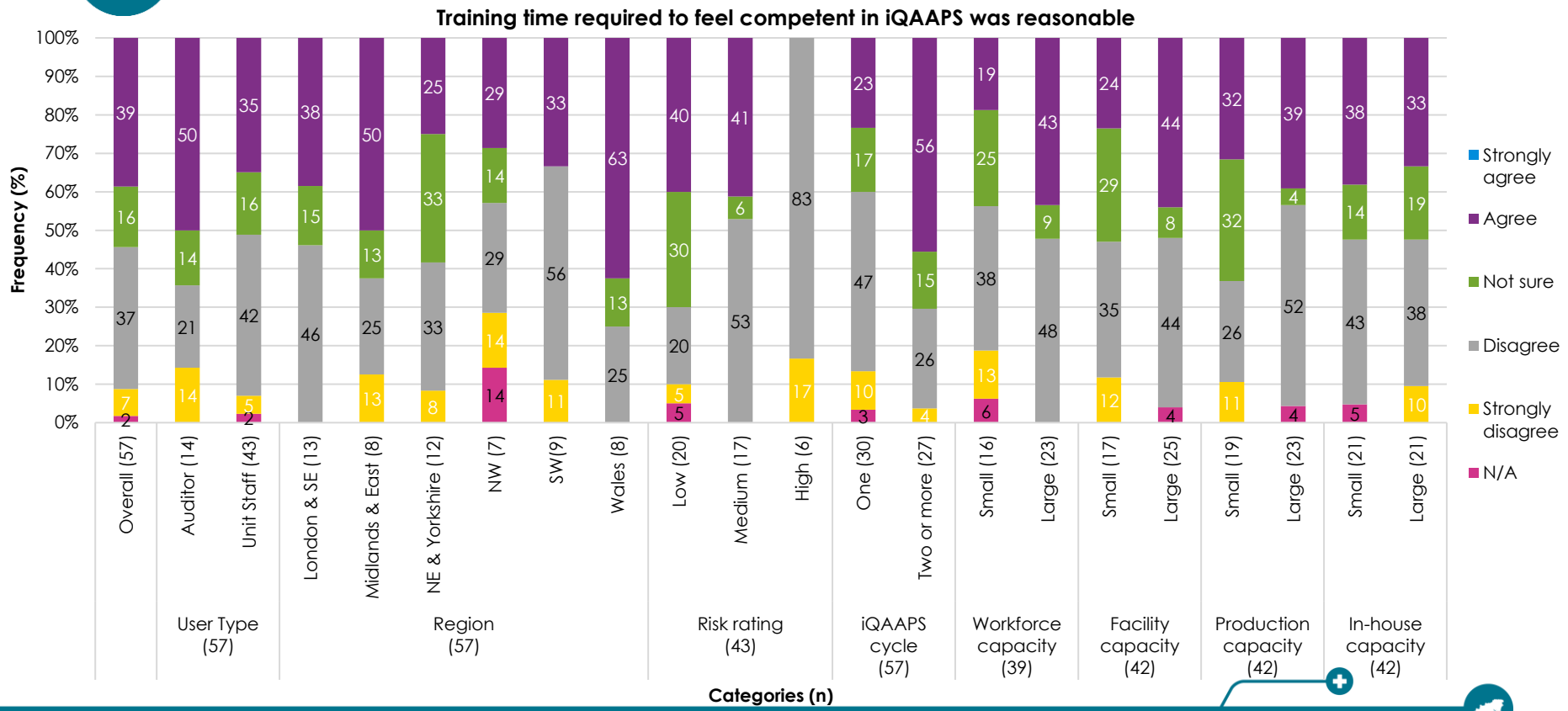
iQAAPS training

- All auditors, Chief Pharmacists and unit staff (Accountable Pharmacists) were offered face-to-face or online training to use iQAAPS.
- Various training materials were developed and made available:
  - iQAAPS Aseptic Unit Training slidedeck
  - iQAAPS Site User Guide
  - iQAAPS Auditors Guide
  - Seven training videos: https://www.quiqsolutions.com/iqaaps-guides
- Of the Chief Pharmacists in England involved with iQAAPS (n=113), 22% attended a face-to-face training session, 37% declined the face-to-face training session, and 41% were provided a pre-recorded training session online.
- Of the Accountable Pharmacists in England involved with iQAAPS (n=122), 37% attended a face-to-face training session, 23% declined the face-to-face training session, and 40% were provided a pre-recorded training session online.

Views on iQAAPS training



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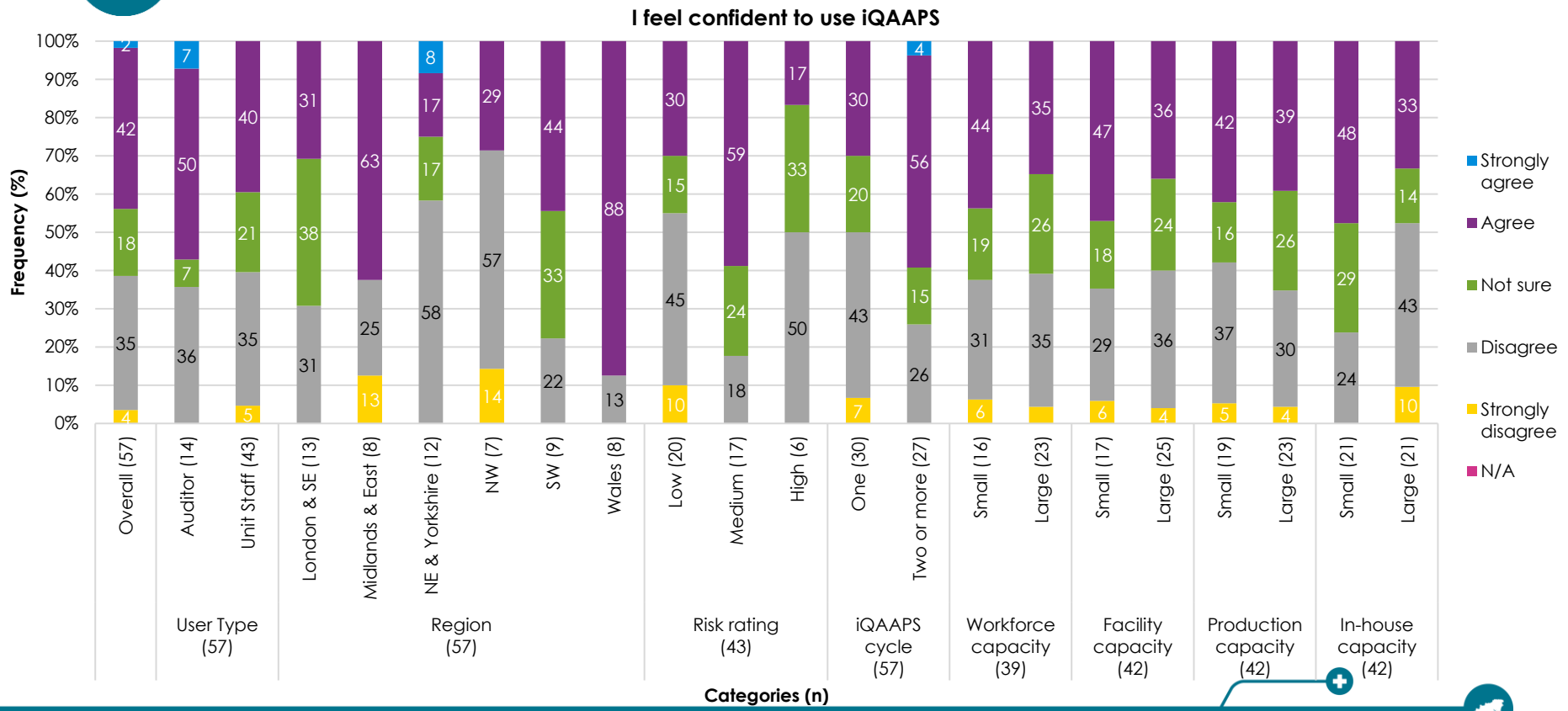
Views on iQAAPS training



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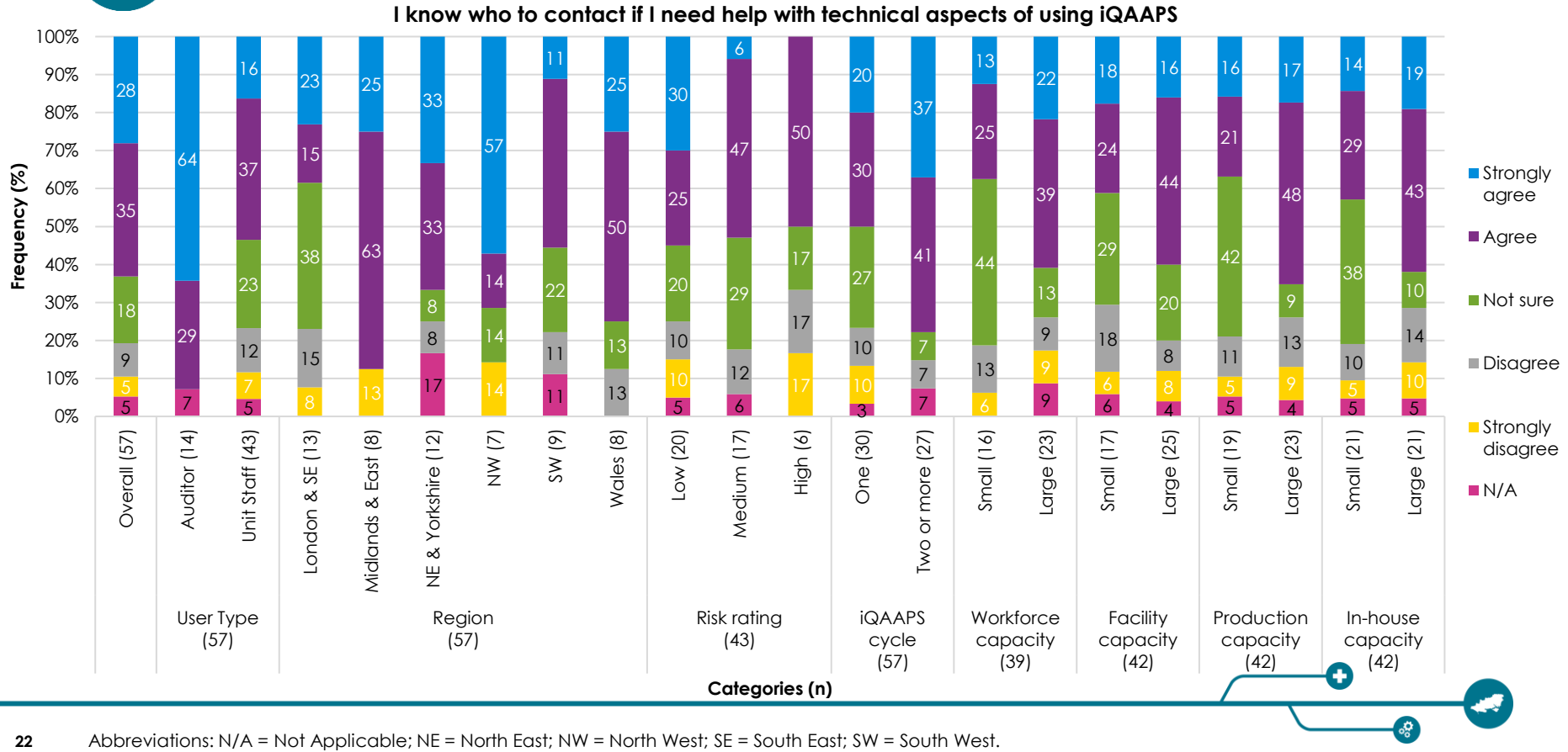
Views on iQAAPS training



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Views on training

- **Good communication from SPS team:** "The support provided by [SPS team member] is fantastic. Issues are resolved quickly and with good humour. If it wasn't for [SPS team member], use of iQAAPS would be very difficult and more complaints and queries from auditors and auditees due to frustrations using the system would have arisen." (Auditor)

- **Concerns about limited training:** "There has been a lack of training, I've been using iQAAPS by trial and error." (Unit staff)
  "The training was delivered with several months between it and the first audit I did using iQAAPS, so I'd forgotten most of it. As a result I've found it very difficult to get the hang of it." (Auditor)
  "The action planning tool isn't fit for purpose and didn't work properly. There hasn't been enough training or explanation of this part of the system so I don't feel I fully understand how I should be using it." (Unit staff)

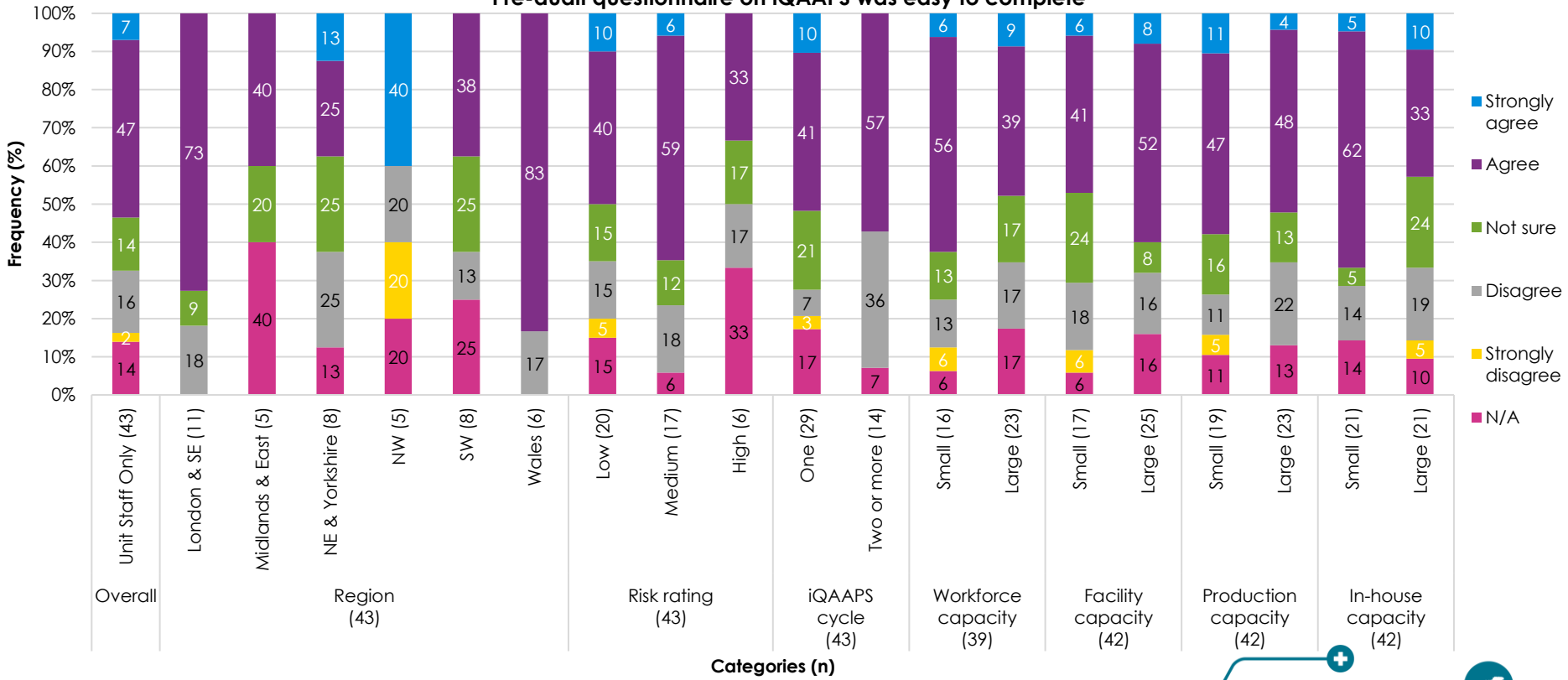
- **Timing of training:** "Training was only provided in August so I couldn't attend." (Auditor)
  "I will be watching the training video again now we are using rather than it being theoretical." (Unit staff)

- **Training delivery format:** "I have watched back many sessions but it's not the same and didn't give me the opportunity to work along or ask questions." (Auditor)
  "I would have preferred audio on the training videos." (Unit staff)

- **Capacity to engage with iQAAPS guidance:** "It was something new and getting the time for training was challenging…getting all staff to use it on a day-to-day basis, some of my team are copied into action plans and responses but they don't use, add notes or upload to the system every day, so it becomes more difficult to retain the training." (Unit staff)

- **Essential responsibility of staff to engage with iQAAPS guidance:** "I found creating the action plan was very time consuming with a lot of duplication but this might be because I don't know how to use the system properly e.g. I wrote the same action against a number of the standards." (Unit staff)

Views on Pre-Audit Questionnaire process



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Views on system access

A range of mixed findings on iQAAPS system access were reported.

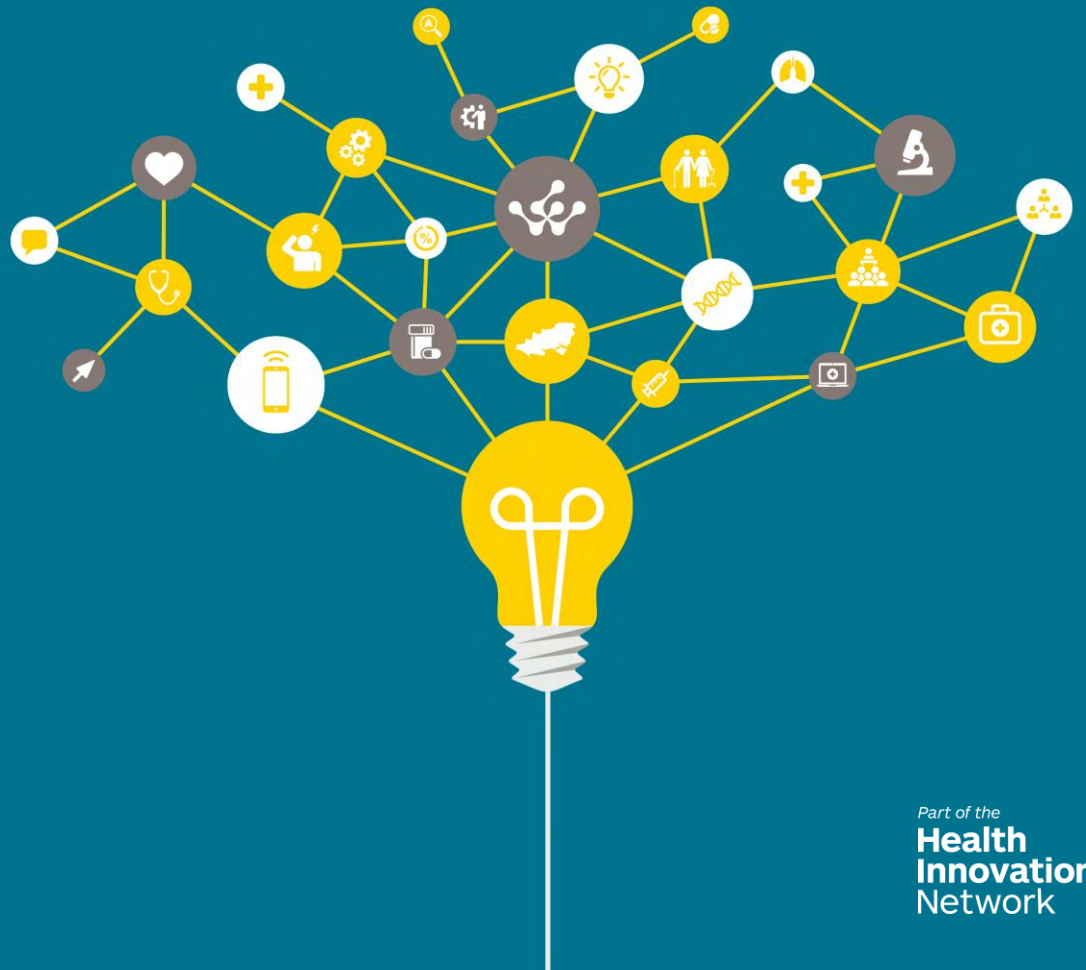
- The vast majority (92%, strongly agree and agree combined) of respondents reported the iQAAPS login process was quick and easy.
- Most (67%, strongly agree and agree combined) respondents reported they could easily upload documents on iQAAPS.
- Slightly under half (44%, strongly agree and agree combined) of respondents reported they could easily edit information on iQAAPS and this was higher (88%) for staff in Wales using iQAAPS.
- Nearly half (46%, strongly disagree and disagree combined) of respondents reported they could not easily find the right information on iQAAPS. This was less so for some regions but high-risk units reported this issue at an even higher level (83%).
- Over a third (39%, strongly disagree and disagree combined) of respondents reported it was not easy to export information from iQAAPS.

Please see Appendix C for data tables.

Section Summary: Training, Pre-Audit Questionnaire, System access

- 44% (strongly disagree and disagree combined) of respondents reported a lack of sufficient training time was available to feel competent in using iQAAPS. Considerable variation in views was observed, e.g. all respondents linked to high-risk sites reported a lack of sufficient training time.
- 44% (strongly agree and agree combined) of respondents reported they were confident to use iQAAPS. Confidence was much higher for auditors compared to other roles, and staff who had used iQAAPS more than once. Some regions were much less confident than other regions and this may be due to fewer training opportunities or engagement.
- 63% (strongly agree and agree combined) knew who to contact to receive iQAAPS technical support. Auditors (93%) were much more certain than unit staff (53%) and regional variation was also apparent.
- Good communication from the SPS team was noted but a range of concerns were also reported: concerns about limited training, the timing of training, the training delivery format, and unit staff and auditor capacity to engage with iQAAPS guidance.
- It was also noted, due to the complexity and detail within a QAAPS audit, there is an essential responsibility of staff to engage with iQAAPS guidance.
- Most unit staff (54%) agreed the Pre-Audit Questionnaire was easy to complete via iQAAPS. Some noted it asked for more information than previous audits, needed more time to gather relevant documents, and had some minor problems with uploading documents.
- A range of positive findings and concerns about iQAAPS system access were reported.

The audit process



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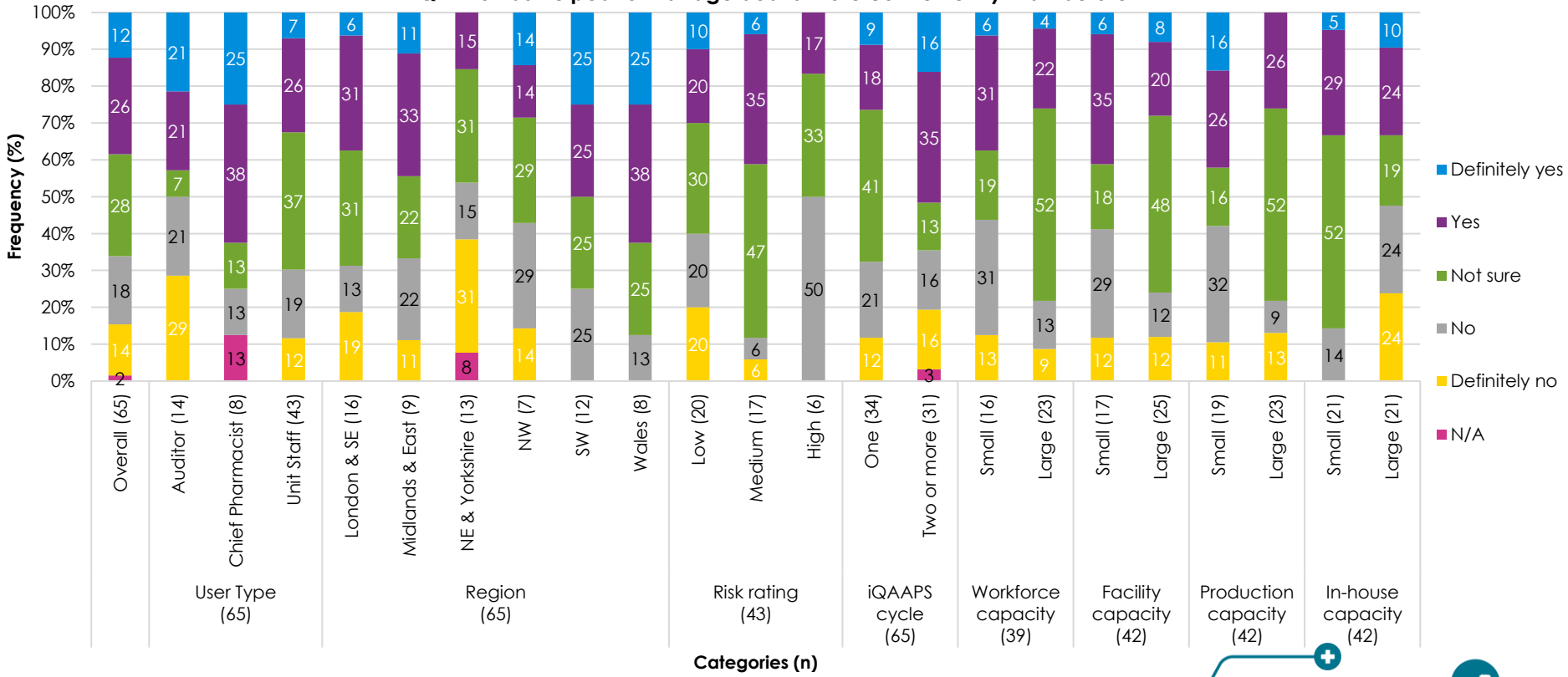
Perceptions of the audit process



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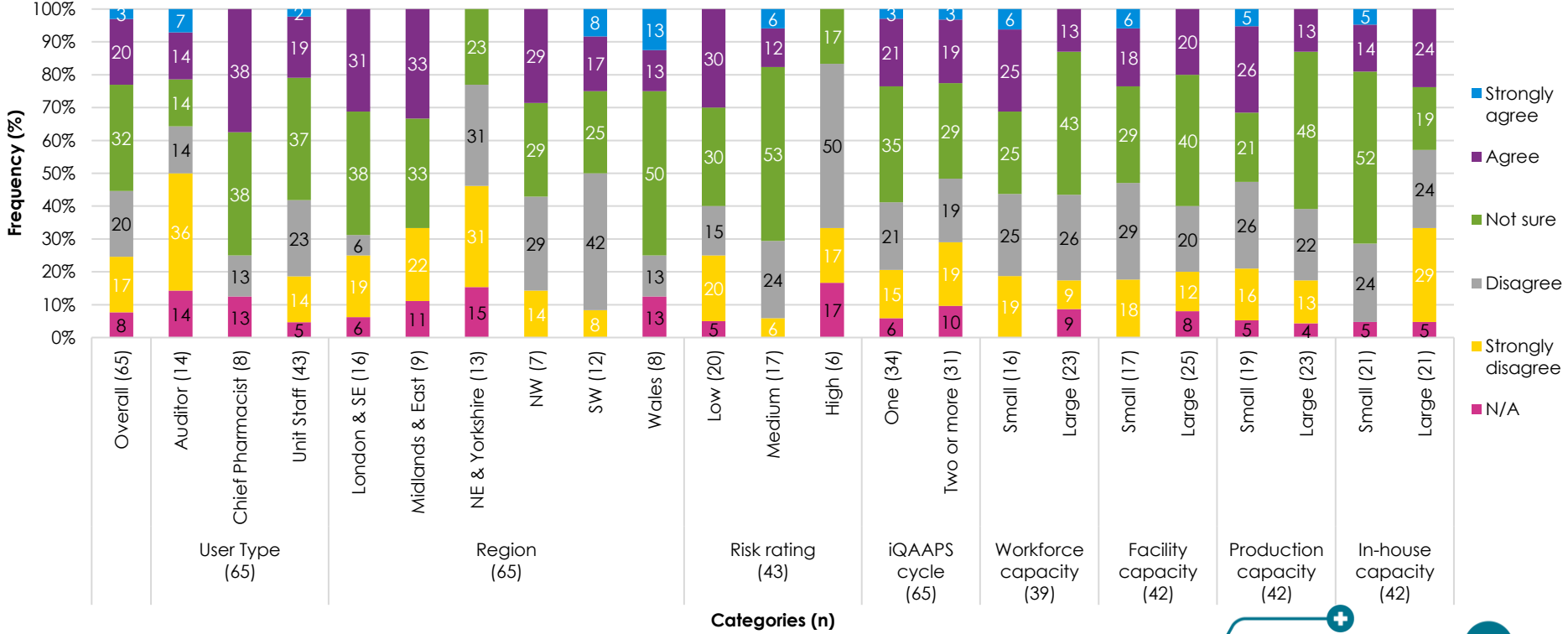
Perceptions of the audit process

iQAAPS improved the time taken to receive and respond to an audit (from pre-audit questionnaire to completion of actions)



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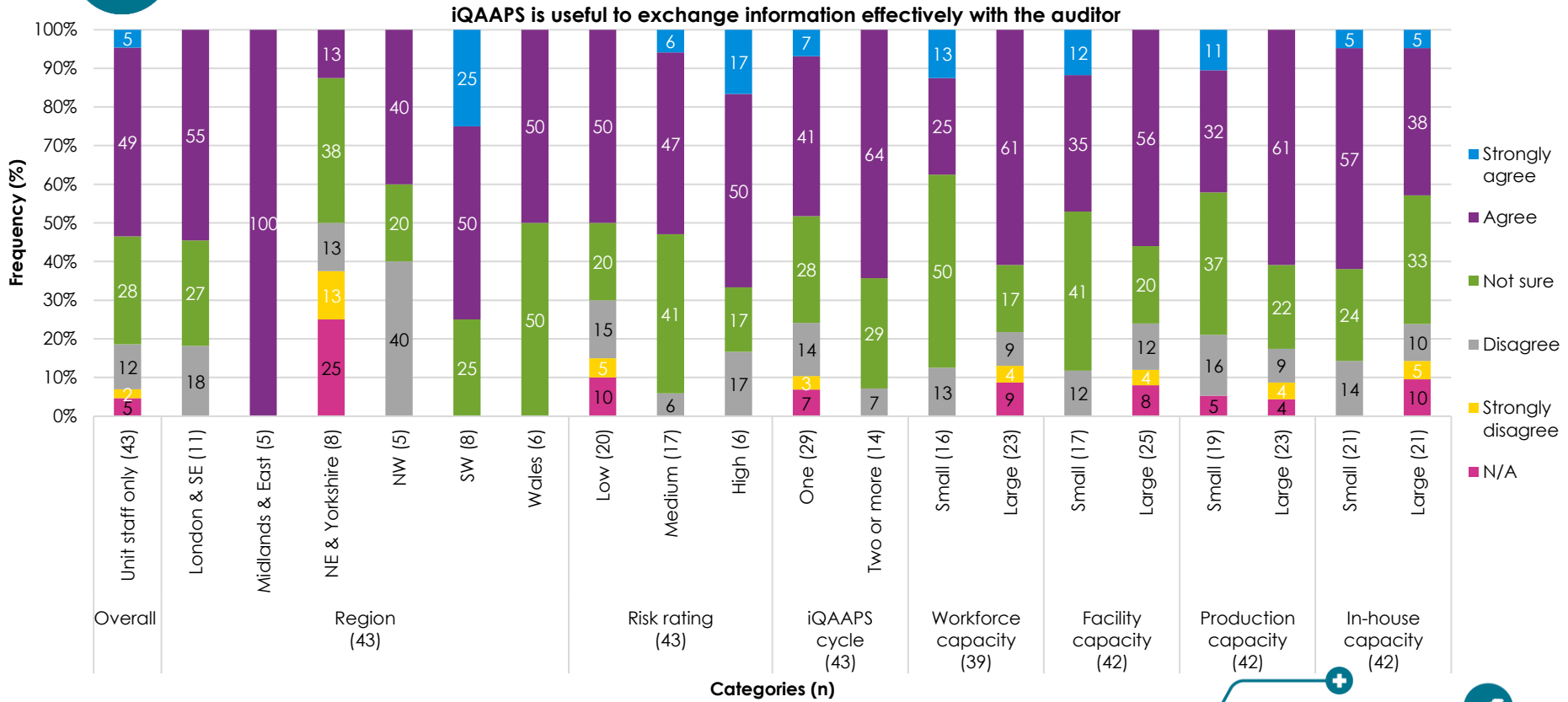
Perceptions of the audit process



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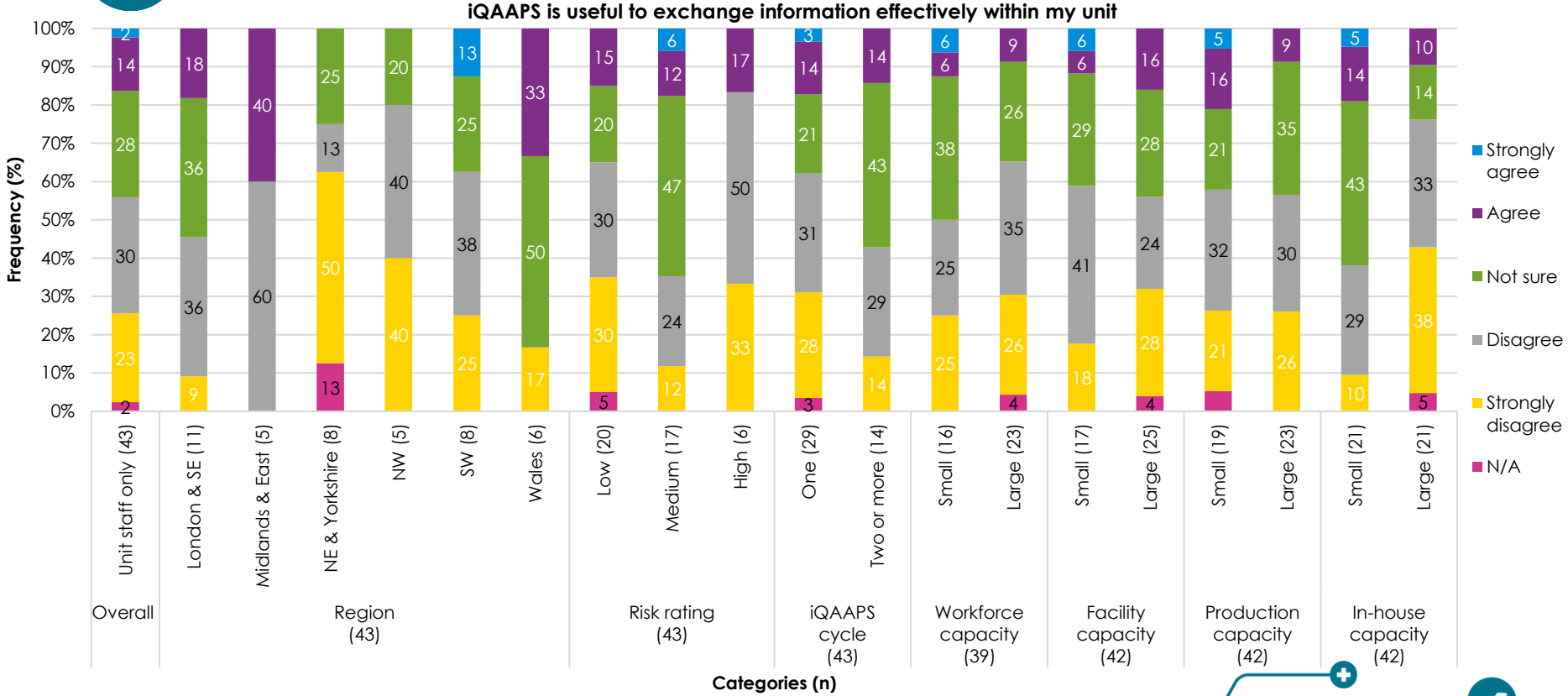

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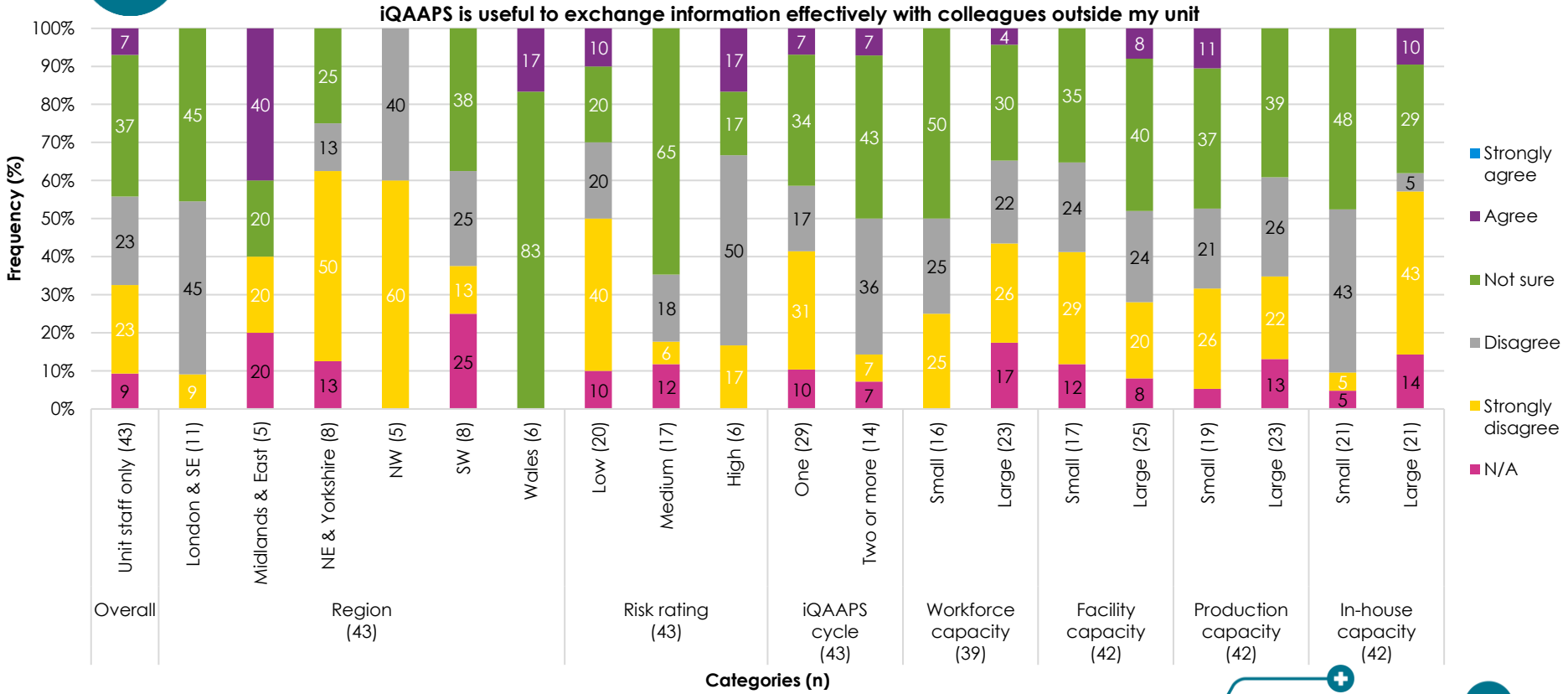
Perceptions of the audit process



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Concerns about the audit process

- **Ease of navigation concern:** "The iQAAPS dashboard shows the risk rating of each chapter, and marks to indicate actions required by the units. There isn't a view that shows the auditor what their own next actions are, e.g. send Chief Executive summary. QAAPS standards can be similar or repeated in different chapters, and definitely not seen in chapter order at the audit visit. There isn't a way of navigating efficiently to the required standard. We have to rely on memory and inevitably do a lot of scrolling about." (Auditor)
  "It is easy to miss steps that are required to progress the audit, e.g. if the auditor or auditee does not click a button then the action plan does not progress." (Auditor)

- **Duplication concern:** "Duplication of a number of standards that makes the write up difficult. The same deficiency can be reported in a number of different places if the report is not checked thoroughly." (Auditor)

- **'Having the required information in front of me' concern:** "[There is an] inability to look at the standards, the deficiency and the action plan in the same field of vision. This makes checking the action plan very time consuming and can lead to errors." (Auditor)

- **Colleague coordination concern:** "For audits conducted by two or more team members, we are not able to work on the report at the same time, delaying completion of the report." (Auditor)
  "If I assign a task to someone else, I can no longer edit or update the task." (Unit staff)
  "I am unable to assign actions to the appropriate team member on iQAAPS as we are restricted to the number of users [licences] that we can have. The restriction on number of users means at present it isn't a practical system for us." (Unit staff)

- **Inefficiency concern:** "We still use a paper aide-memoire as a prompt and to record findings during the audit, then transcribe into iQAAPS afterwards. I would like to be able to input findings directly to iQAAPS in real time during the audit, then just tidy up afterwards. This would reduce the time spent on producing the report, but internet connectivity often isn't reliable enough and it isn't practical to take a laptop when walking around the unit." (Auditor)
  "Fewer staff have access to system than we need to give actions to, so we are having to find a way to duplicate or triplicate action plans on alternative system, an Excel spreadsheet and Q-Pulse [quality management software], with concerns about how to keep all up to date." (Unit staff)

Section Summary: Perceptions of the audit process

- Only 38% (responding definitely yes or yes) of respondents stated iQAAPS was **more convenient** than before, suggesting its potential to save time and be an efficient audit method is yet to be realised. Unit staff were the least positive and Chief Pharmacists the most positive. Regionally, iQAAPS was not perceived as more convenient in North East & Yorkshire and North West regions. The capacity variables indicate that if a unit has small workforce, facility and production capacities, they do not view iQAAPS as convenient. Units with large capacity don't seem to have general stance (i.e. majority reporting as 'not sure') whether iQAAPS is convenient or not compared to previous auditing methods. A similar pattern of findings were found about whether iQAAPS had improved the total time taken from receiving notification of an audit and completion of any actions.

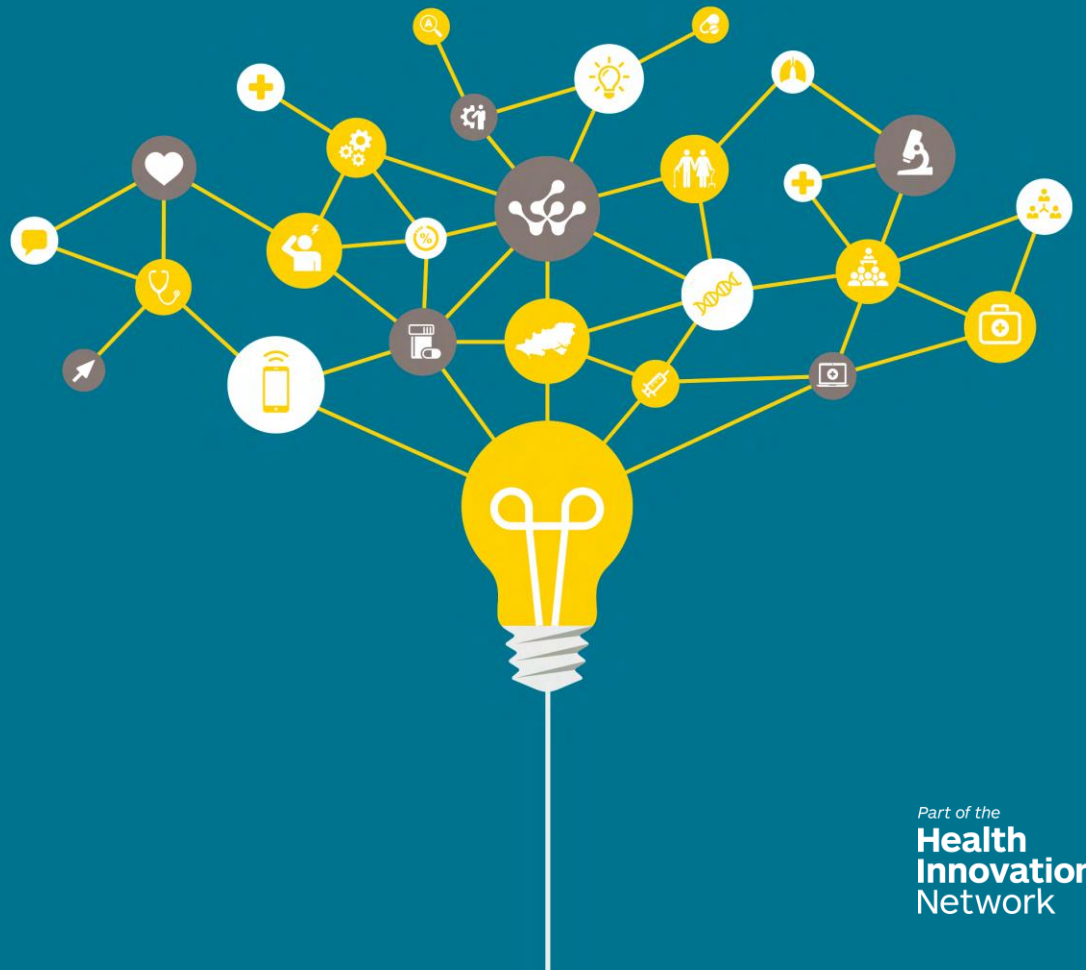
- 54% (strongly agreed or agreed) reported iQAAPS was effective at **exchanging information with auditors**. Regional variation was again apparent and units with larger workforce capacity agreed more (61%) than units with small workforce capacity (48%).

- **Exchanging iQAAPS information within units** was perceived difficult to do. 53% (strongly disagreed or disagreed) stated it was hard within their unit and this increased to 83% for high-risk units. The latter would suggest a larger list of actions exacerbates the existing limitations.

- **Exchanging iQAAPS information outside of units** was also perceived difficult to do. 46% (strongly disagreed or disagreed) stated it was hard and this increased to 67% for high-risk units. All respondents from the North West region reported this was difficult.

- A range of concerns about how iQAAPS supports the audit process were identified.

The audit outputs



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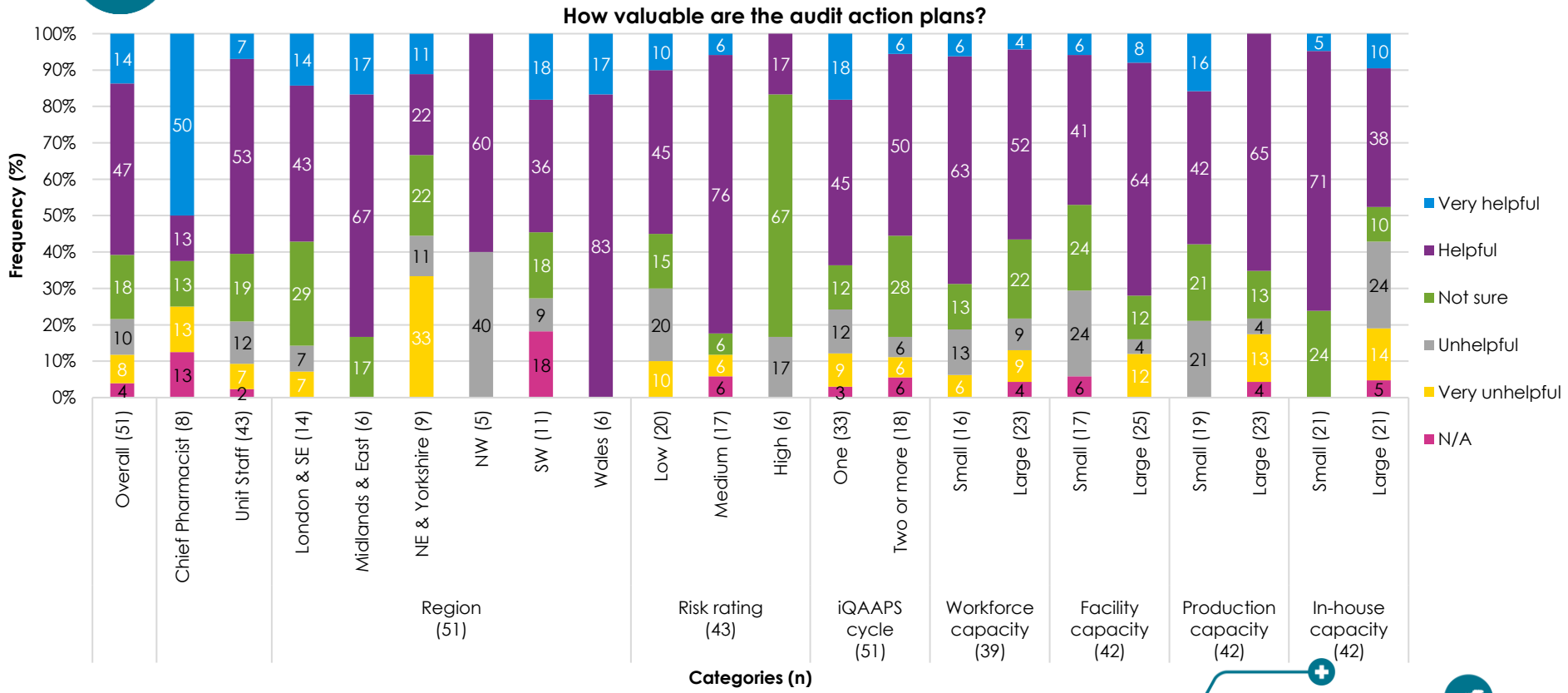
Perceptions of the audit outputs



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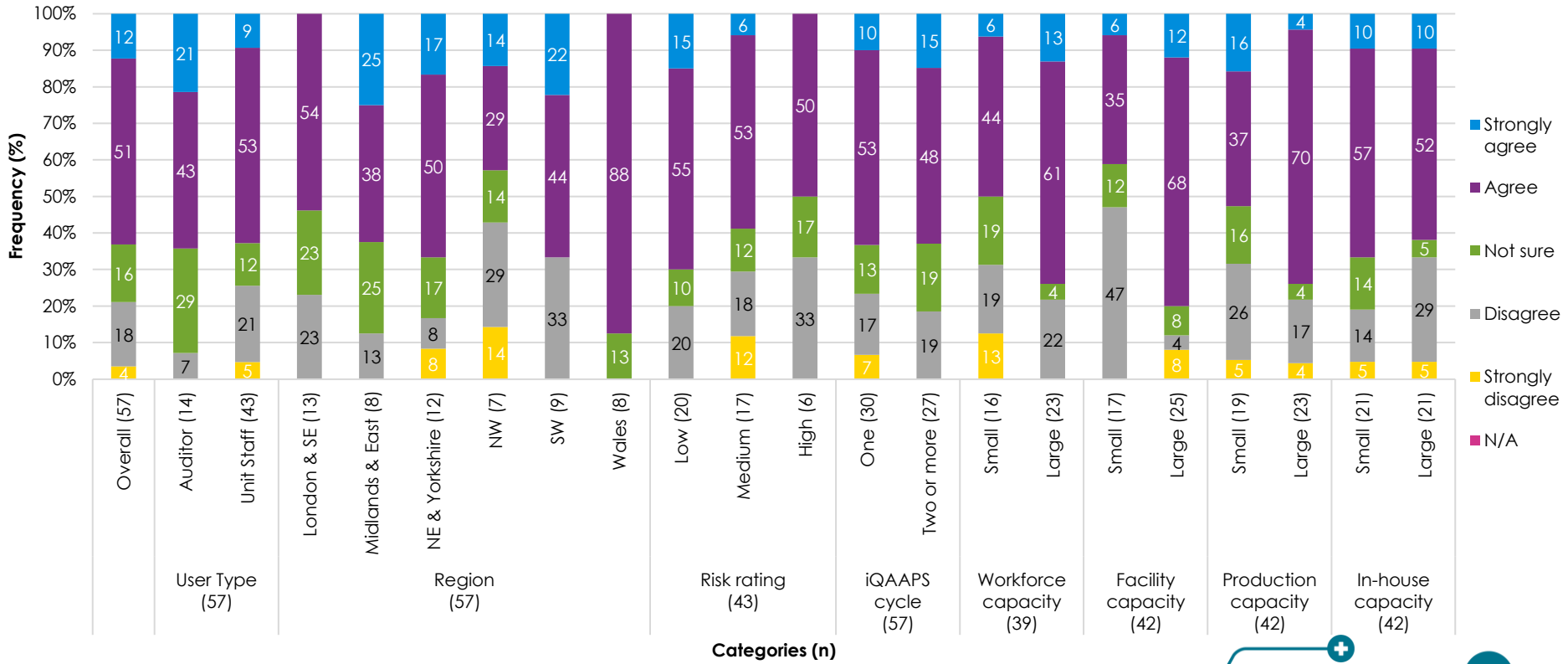
Perceptions of the audit outputs



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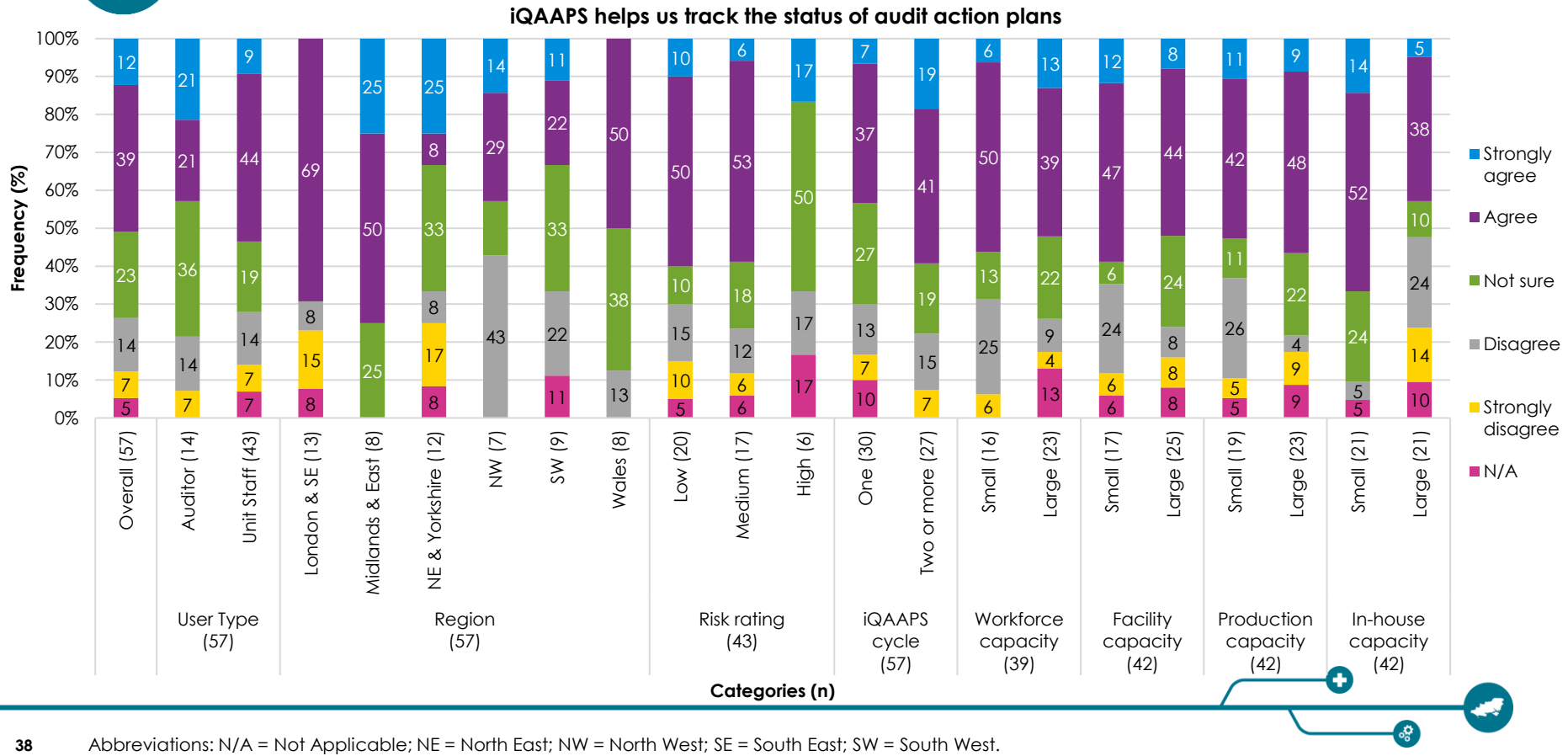
Perceptions of the audit outputs



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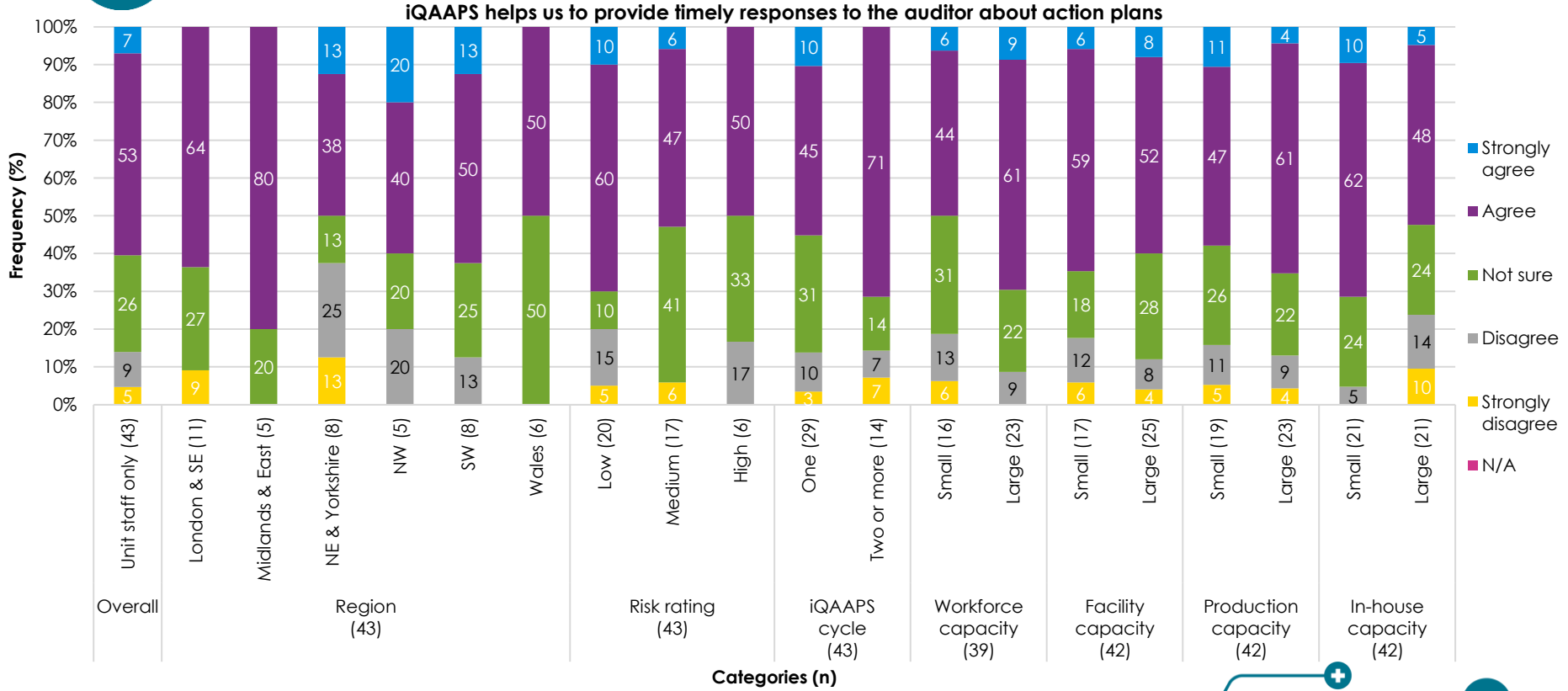
Perceptions of the audit outputs



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Perceptions of the audit outputs

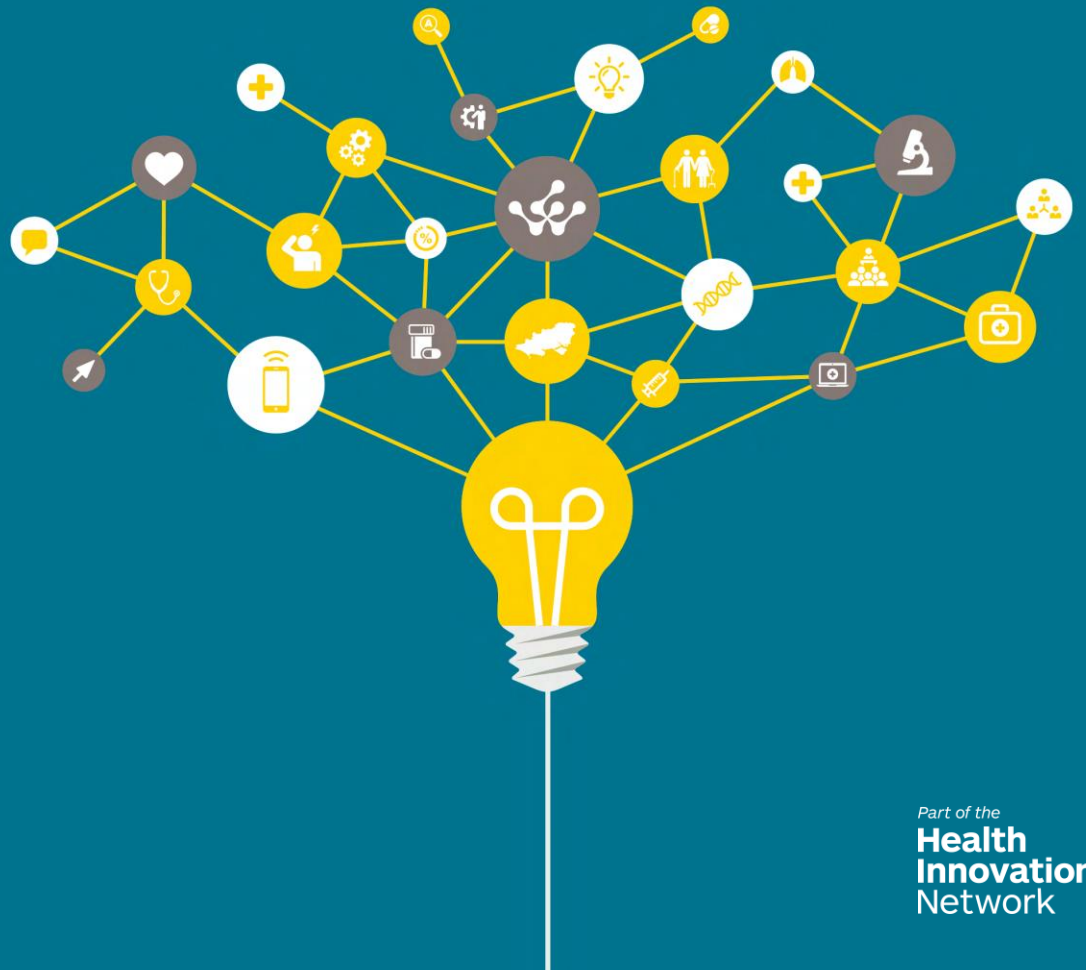
Mixed findings on iQAAPS outputs were reported:

- **Increased audit quality:** "I really like the system. I think once you get used to how it works it is a massive improvement. It helps with closing out actions and I like the alignment for everyone and the oversight it offers to the Chief Pharmacist, quality assurance colleagues at region level, and the Specialist Pharmacy Service. I feel it is a supportive move forward for Accountable Pharmacists." (Unit staff)
- **Increased transparency:** "[The outputs are] very valuable, ease of use and all output reports are available for the team to use." (Chief Pharmacist)
- **Increased assurance:** "We can remotely view live action plans and check progress with ability to do this before review meetings for high-risk units. This gives greater assurance the actions are progressing." (Auditor)
- **Saved time:** "I can complete parts of the action plan independently, so we are not relying on having to meet and go through paper logs and action plans like in the past. The reminders are helpful too." (Unit staff)
- **Uncertainty of accurate information sharing:** "Review and approval of action plans is difficult and feels more complicated than it should be. If an item in the action plan requires more work, I'm still not clear that I have recorded this correctly and always contact the site directly to ensure they are aware of the 'non-approval'." (Auditor)
- **Limited shareability of action plans:** "Having a readable audit plan for the governance group. Currently the exported version does not display all the required information." (Unit staff)
- **Multiple action plan challenge:** "The action plans are saved individually so this means I now have 80 action plans." (Unit staff)

Section Summary: Perceptions of the audit outputs

- Overall, 61% of respondents indicated the **audit action plans were valuable**. Variation in views was observed with only 33% of North East & Yorkshire region respondents and 17% of high-risk units respondents indicating action plans were helpful.
- Overall, 63% of respondents reported iQAAPS **clearly identifies actions required**. The only variation seen was in the North West region, for high-risk units, and units with a small facility capacity.
- Overall, 51% of respondents reported iQAAPS **helped keep track of the status of audit action plans**. This was broadly similar across different stakeholders and contexts, except in the North West in which 43% disagreed and 50% of staff at high-risk units were uncertain.
- Overall, 60% of unit staff reported iQAAPS **helped to provide timely responses to the auditor about action plans**. This was broadly similar across different stakeholders and contexts, except staff in the Midlands & East (80%) and at low-risk units (70%) were more certain.
- Respondents reported increased audit quality, transparency, assurance and saved time was facilitated by iQAAPS.
- A range of concerns about iQAAPS outputs were identified, including uncertainty whether unit staff were seeing auditor comments on action plans, not having a shareable action plan for senior colleagues and concerns from high-risk units about how to manage large volumes of action plans.

Impact of iQAAPS



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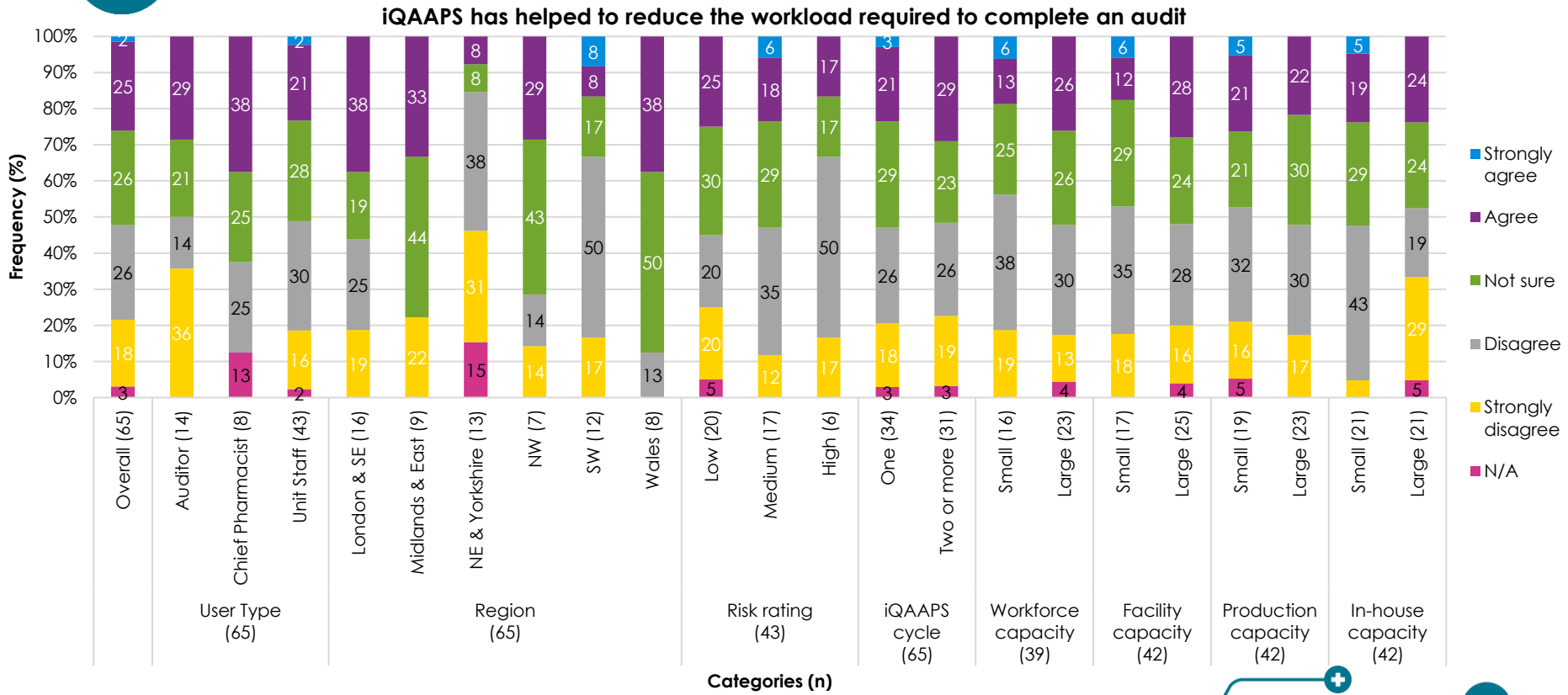
Impact of iQAAPS on workload



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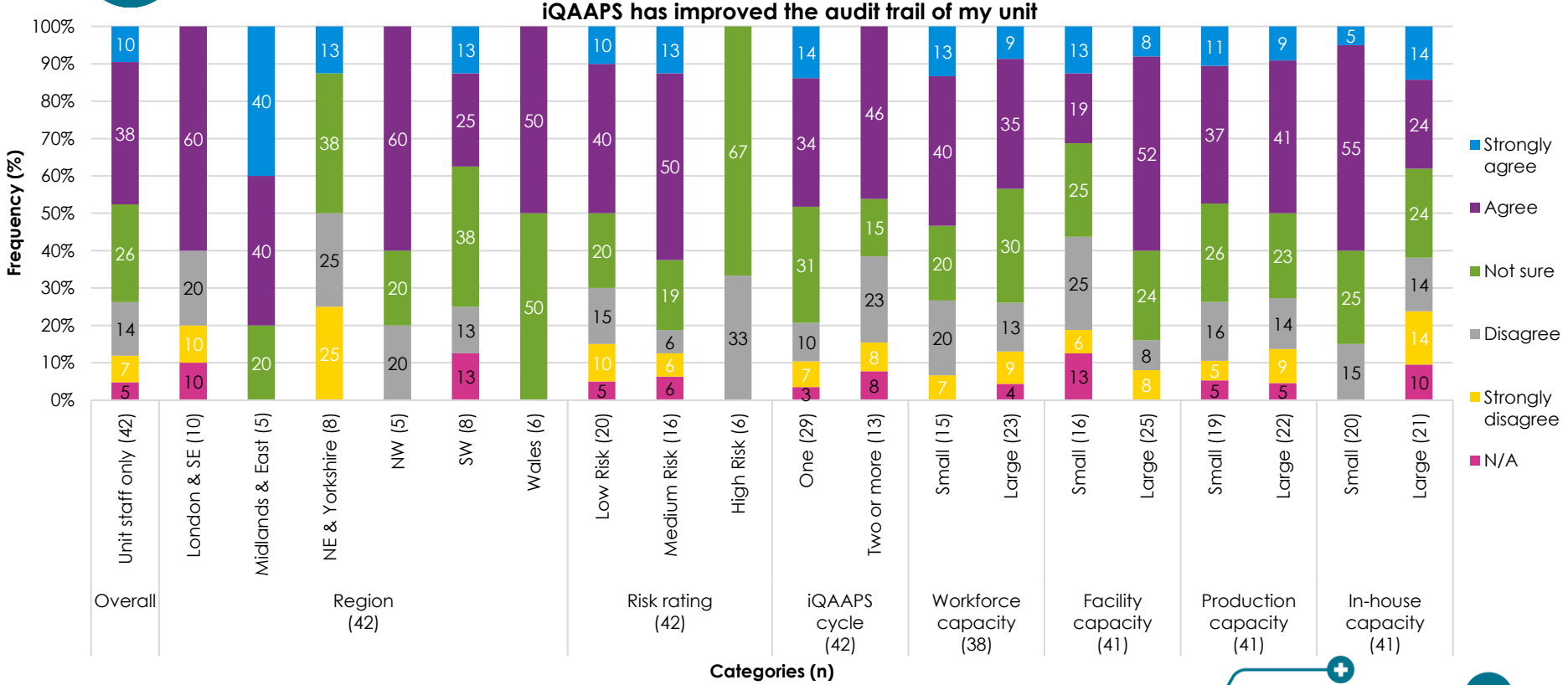
Impact of iQAAPS on workload



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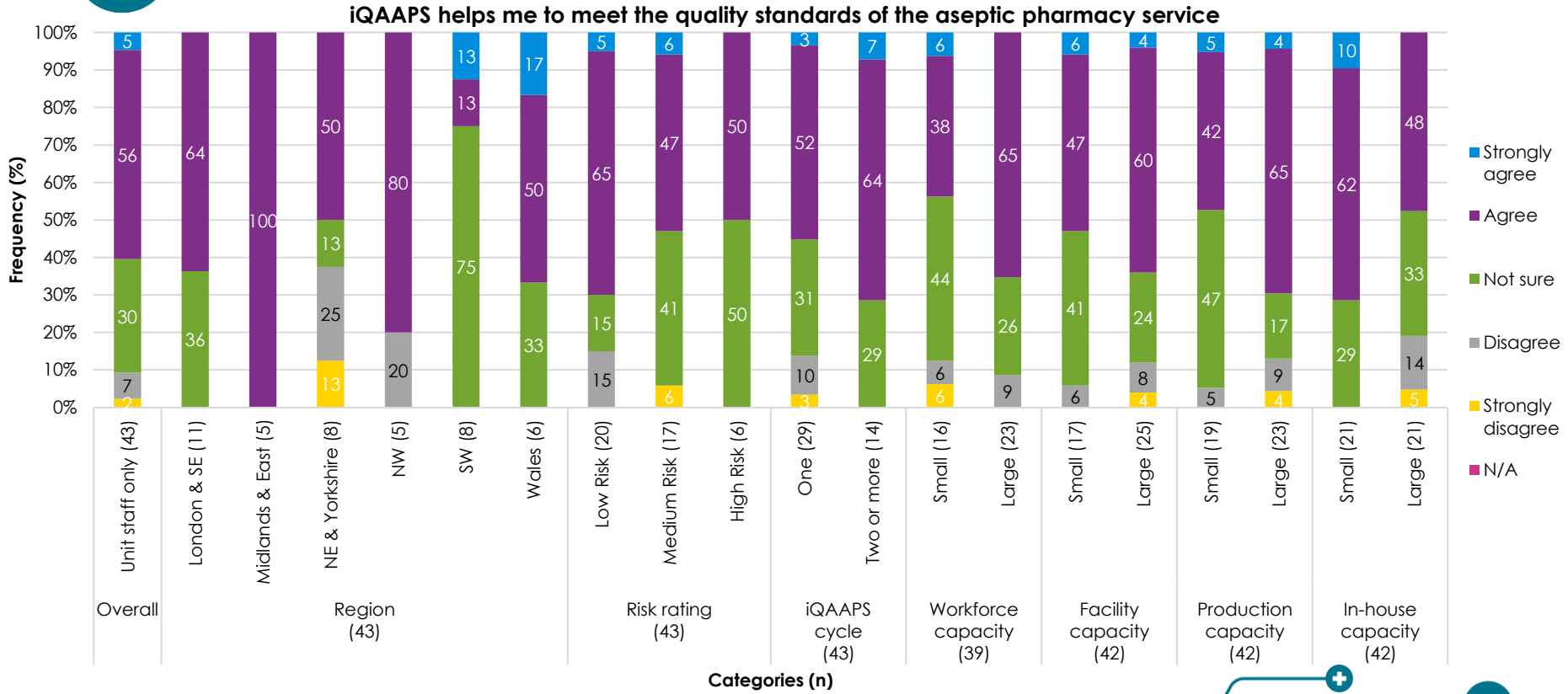
Impact of iQAAPS on quality assurance



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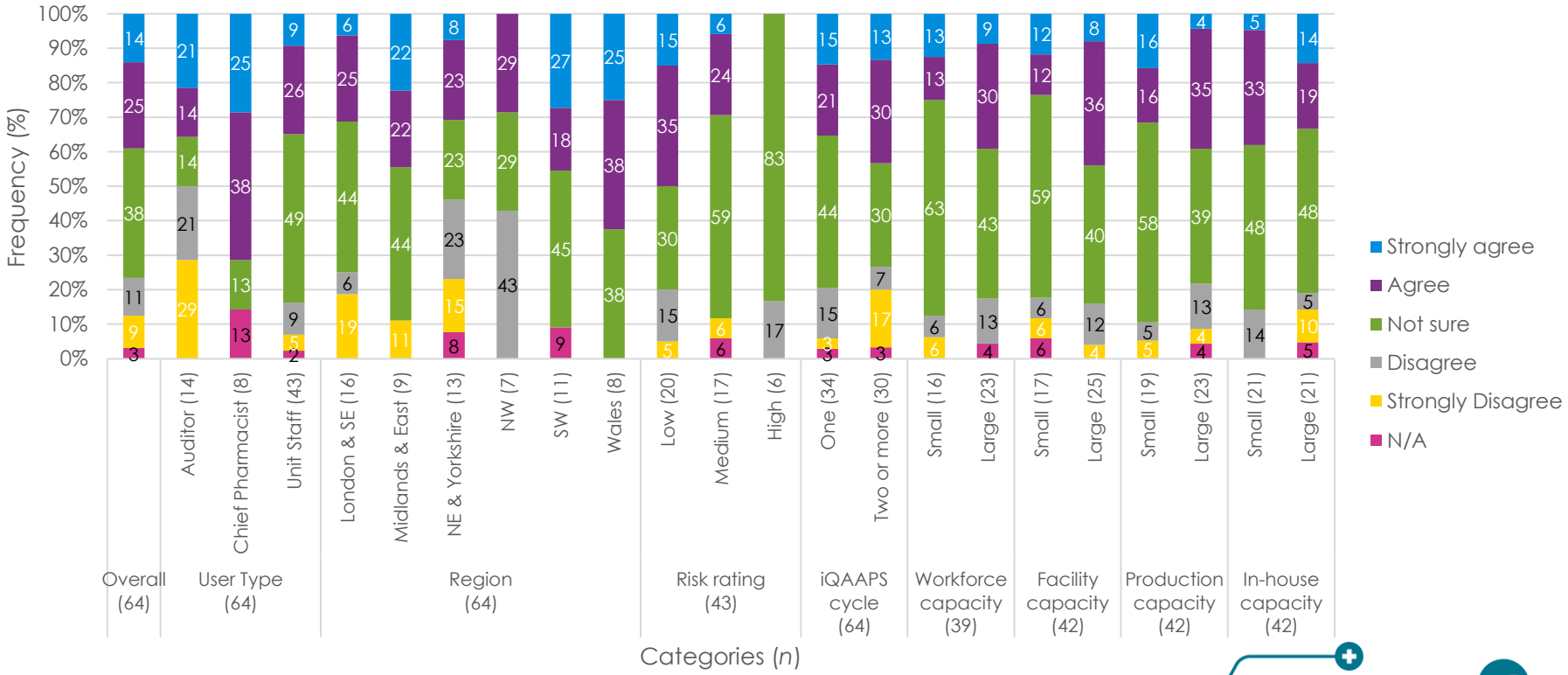
Impact of iQAAPS on quality assurance



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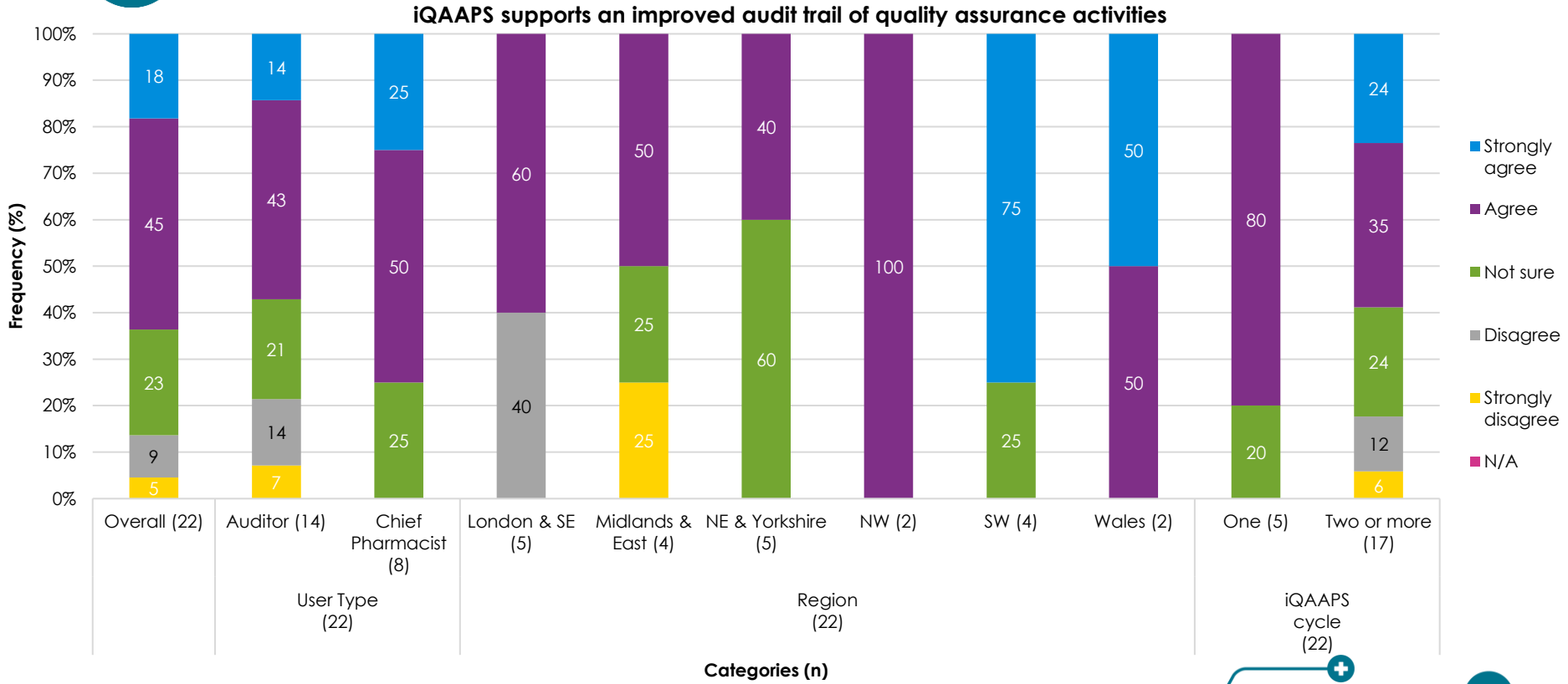
Impact of iQAAPS on quality assurance



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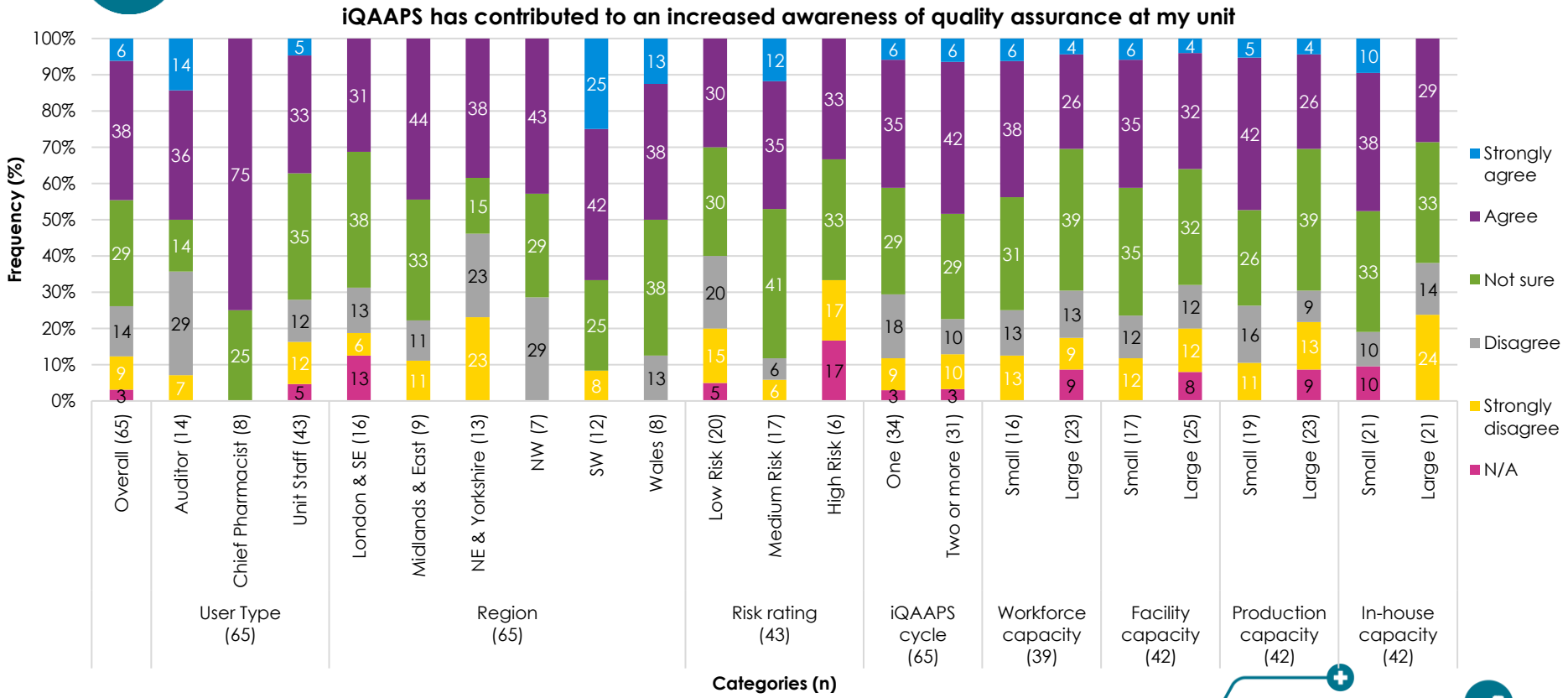
Impact of iQAAPS on quality assurance



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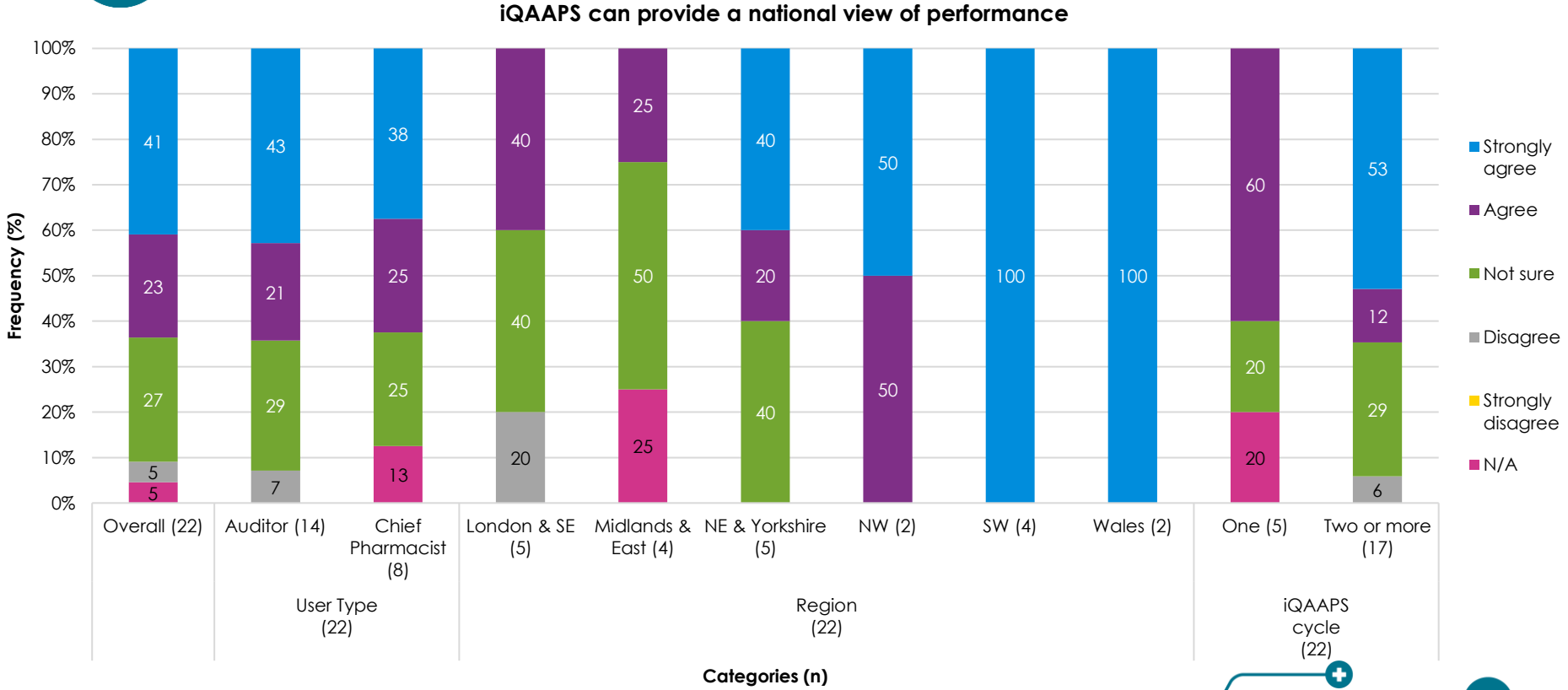
Impact of iQAAPS on oversight of audit activities



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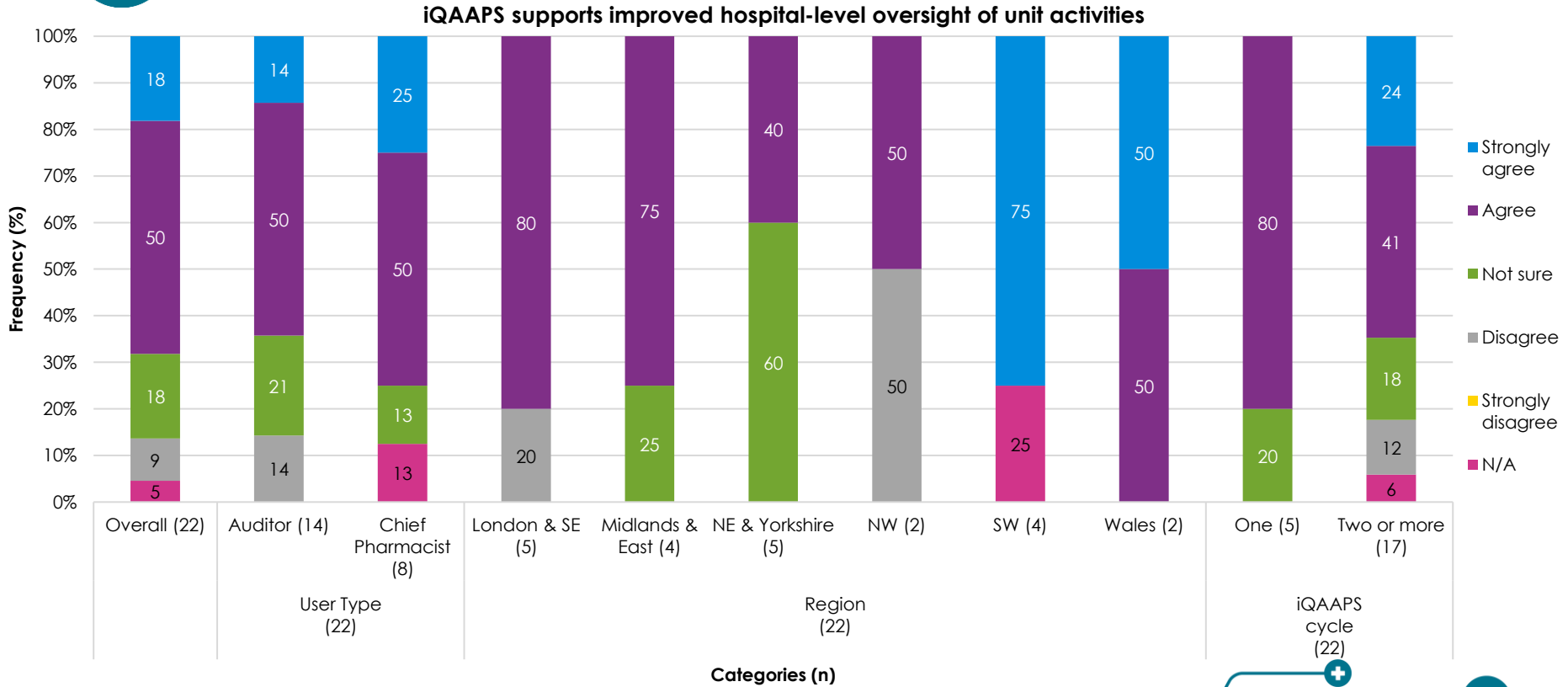
Impact of iQAAPS on oversight of audit activities



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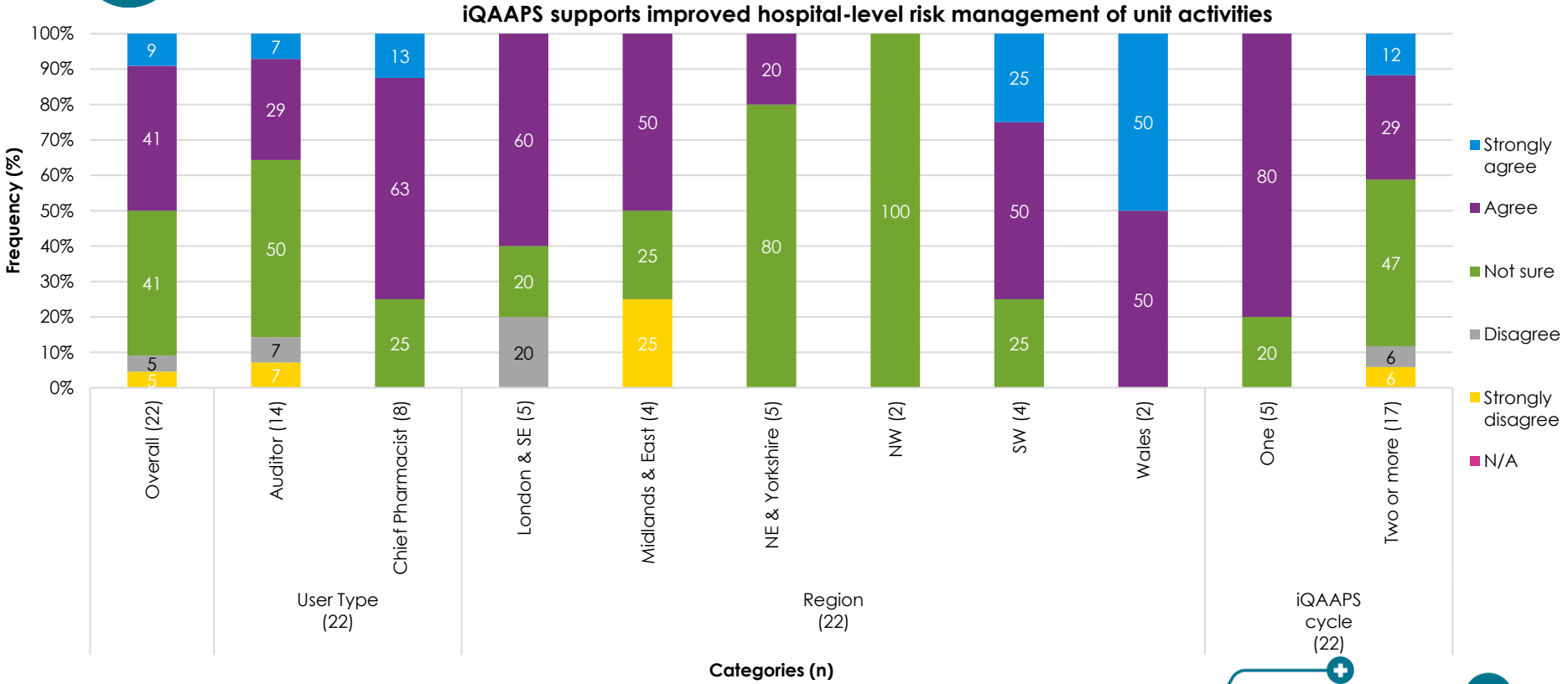
Impact of iQAAPS on risk management



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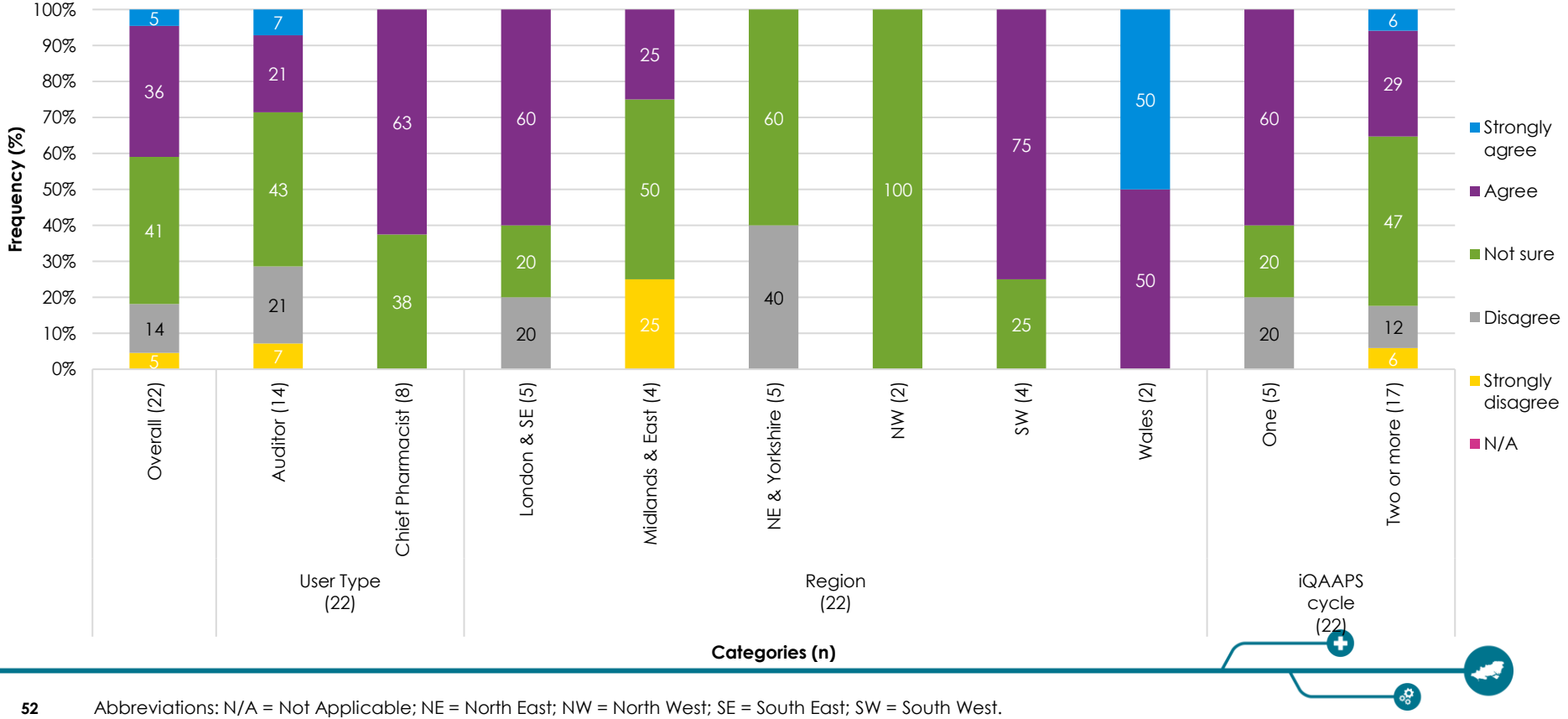
Impact of iQAAPS on risk management



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Impact on aseptic units, unit staff, and auditors

Several themes were reported in the survey free text feedback:

- **Welcomed rigour:** "The process is essentially much more structured now; previous audits were rather subjective." (Unit staff)
- **Time needed to complete an iQAAPS-supported audit:** "Keeping to deadlines and updating the system regularly has had a positive and negative impact on the staff, in that the system shows and informs what and when needs doing but negatively, staff can feel pressurised and anxious especially if there has been slippage due to circumstances out of their control." (Unit staff)
- **Time trade-off:** "The time taken to do audits has increased, which has decreased our capacity at the unit a bit." (Unit staff)
- **Time needed to actively engage with iQAAPS:** "I know that in time it will be beneficial. I just don't feel so comfortable with it yet as need more time to work on it." (Unit staff)
- **Unit capacity limits iQAAPS engagement:** "We do not use it to its full advantage due to capacity issues and other work pressures." (Unit staff)
- **Capacity management support from the perspective of the Chief Pharmacist:** "iQAAPS has been used as part of the capacity demand modelling at our unit." (Chief Pharmacist)
- **Increased stress for auditors:** "I like the idea of iQAAPS but I've really struggled with the implementation. I found the whole thing very stressful and quite isolating. So much so I have been guilty of putting off writing up reports using iQAAPS to concentrate other jobs which are less stressful." (Auditor)

Wider impact

- 55% of respondents reported the **iQAAPS auditing tool could be useful in other areas** of pharmacy or healthcare services.
- Suggestions from Chief Pharmacists included pathology and blood science services that operate to very specific standards and key performance indicators. Also, training and education credentialing, General Pharmaceutical Council (GPhC) inspections, Royal Pharmaceutical Society (RPS) hospital pharmacy standards self-inspection, Wholesale Dealer's Licence (WDL) self-inspection, Home Office Controlled Drugs Licence inspection, CQC regulation 12 self-assessment, and management of Wholesale Dealer Licence in procurement.

"This kind of platform could be used for any audit, healthcare or otherwise. The questions and standards would simply need to be adapted." (Auditor)

"iQAAPS could be very useful as an audit tool for auditing suppliers." (Auditor)

"I am sure it could have other applications but a degree of self-adaptation by a trust to suit their requirements would be necessary for this to be feasible." (Unit staff)

Wider impact

There was limited feedback on wider impacts beyond the aseptic units; however, a few comments were made and should be considered in future assessments of iQAAPS.

- "The iQAAPS audit influenced the development of business plans to achieve better standards like more staff, new units, and some of the audit standards do reference trust policies so we do need to make sure that these are accurate and cover all requirements as well." (Unit staff)
- "Trusts are aware that failure to improved controls in accordance with iQAAPS timelines may lead to elevation of risk categorisation and escalation of management. Where the deficiency requires significant investment for rectification, e.g. improvement to facilities, this may not be possible and it's important they are able to identify mitigation until the required improvements can be implemented." (Auditor)
- "It is to be hoped that the enhanced visibility helps aseptic services assure necessary resources for required improvements."(Chief Pharmacist)

Section summary 1: Impacts of iQAAPS

Impact on oversight and information sharing

- Overall, 64% (strongly agreed or agreed, n=22) reported iQAAPS **provides a national view of performance**. This was more strongly felt in the South West (100%, n=4) and North West (100%, n=2) regions and Wales (100%, n=2), and less so in London & South East and Midlands & East regions.
- Overall, 68% (strongly agreed or agreed) reported iQAAPS **improved hospital-level oversight of aseptic unit activities**. This was more strongly felt in Wales (100%, n=2), and London & South East (80%, n=5), South West (75%, n=4), and Midlands & East (75%, n=4) regions.
- Overall, 63% (strongly agreed or agreed) reported iQAAPS supported an **improved audit trail of quality assurance activities**. This was more strongly felt by Chief Pharmacists (75%), the North West region (100%, n=2) and Wales (100%, n=2).

Impact on workload

- The majority (44%, strongly disagreed or disagreed) reported iQAAPS **had not helped to reduce the workload** required to complete an audit. This disagreement rose to 67% for high-risk units and 69% in the North East region. Additionally, 57% of units with small workforce capacity also disagreed.
- The majority (48%, strongly agreed or agreed) reported iQAAPS **had improved the audit trail** at their unit, 26% were unsure, 21% disagreed, and 5% responded not applicable. Regional variation was again apparent and no high-risk units agreed.

Section summary 2: Impacts of iQAAPS

Impact on quality assurance

- Overall, 61% (strongly agreed or agreed) reported iQAAPS **helped to meet the quality standards** of the aseptic pharmacy service. This was broadly felt across the various contexts explored, except in the North East region whereby the majority (38%) disagreed.

- Overall, 39% (strongly agreed or agreed) reported iQAAPS **helped to improve the quality of audit assessment**. However, 50% of auditors disagreed and 49% of unit staff were uncertain. 63% of Chief Pharmacists strongly agreed or agreed. Staff at high-risk units either disagreed or were uncertain.

- Overall, 44% (strongly agreed or agreed) reported iQAAPS **helped to increase awareness of quality assurance**. Sub-analyses indicated higher agreement from Chief Pharmacists (75%) and staff in the South West region (67%).

Impact on Risk Management

- Overall, 50% (strongly agreed or agreed) reported iQAAPS **supports improved hospital-level risk management of unit activities**. This was more strongly felt by Chief Pharmacists (76%) and staff in Wales (100%, n=2) and the South West region (75%, n=4).

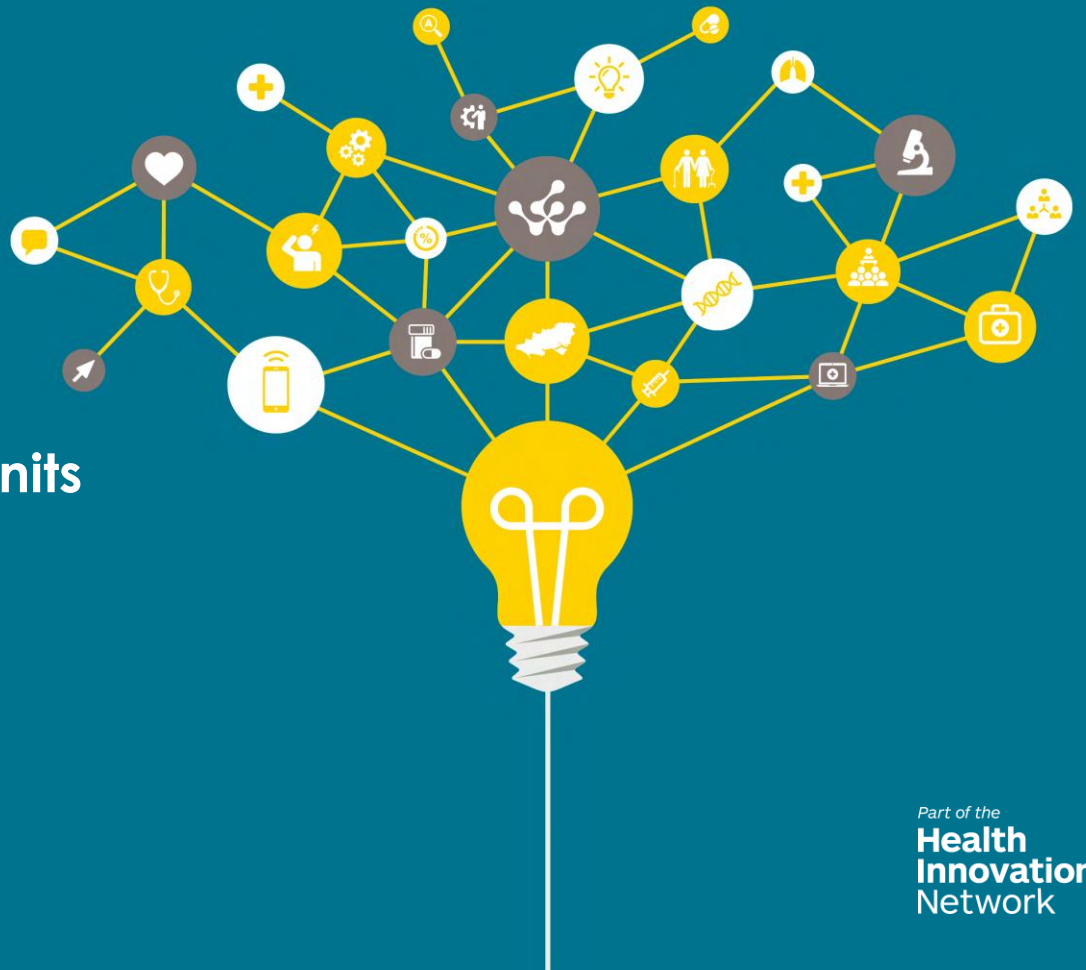
- Overall, 41% (strongly agreed or agreed) reported iQAAPS **supports the ability to appropriately escalate identified unit risks.** This was more strongly felt by Chief Pharmacists (63%) and staff in Wales (100%, n=2) and the South West region (75%, n=4).

Section summary 3: Impacts of iQAAPS

- Several themes were reported in the survey free text feedback, including welcomed rigour to a previously more subjective process.
- However, the additional effort required for an iQAAPS-supported audit meant additional time was needed to complete it; there was a trade-off in time and unit capacity to consider, which for some units was difficult due to general capacity limits. Also, iQAAPS could increase anxiety for unit staff (and auditors) who had not engaged or were unwilling to. The latter highlights that the implementation of iQAAPS involves more than simply introducing a new digital platform, but **for some units (and auditors) iQAAPS represents a cultural shift in audit activities**.
- iQAAPS was described as having **potential value in a range of other areas** of pharmacy and healthcare.

The value of iQAAPS for units with a high-risk outcome

Case studies



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Case studies of high-risk units

- Previously, the survey findings highlighted the increased negativity of staff linked to a high-risk unit. Respondents stated this is related to the volume of actions generated in the iQAAPS system and resultant activity within the unit. It is also exacerbated by previously reported implementation and operational challenges of using iQAAPS.

- Three typologies were apparent across the four case studies of units with a high-risk outcome:
    - Typology 1: iQAAPS valued but limited capacity to audit
    - Typology 2: iQAAPS of limited value and low capacity to audit
    - Typology 3: iQAAPS valued but have capacity to audit.

- The experience, perceived value, and impacts of iQAAPS in the context of a high-risk outcome decision were subtly different across the case study units.

- The only clear difference was in capacity to enact the audit and post-audit actions from a high-risk outcome. In that situation, perceptions of iQAAPS value were lower and more challenges in its operationalisation were reported.

- At present, the benefits of iQAAPS can be downplayed or not realised in the context of units with a high-risk outcome. Special arrangements to support these units would give iQAAPS the opportunity to support sites and be perceived as less of a burden.

Case study 1 (typology 1: iQAAPS valued but limited capacity to audit)

The context

Most recent iQAAPS audit: 2022

Unit capacity profile

- Workforce: Large (~18WTE)
- Facility: Large (~8 clean air devices)
- In-house production: Small (~30%)
- Total production: Large (~24,000 production)

Survey responses

- Overall value of iQAAPS (mean score): 8 (max 10)
- Value of audit action plans (predominant rating): Helpful
- iQAAPS provides oversight (predominant rating): Agree

The perceived value of iQAAPS in the context of a high-risk outcome decision

- High levels of engagement between SPS and this unit were reported and may have facilitated the positive views
- Training was reported as adequate for their needs
- Appreciated the factual, structured, and transparent approach of iQAAPS
- Wide range of staff in unit but limited ability to conduct audits due to large production capacity

The experience of managing the actions from a high-risk outcome decision

- The unit used a companion Excel spreadsheet alongside iQAAPS to manage the 65+ actions and staff allocated to support the actions
- Had to delegate many actions to different staff but this was hindered by the number of licences available and functionality to view other's completed actions

The perceived impact of iQAAPS in the context of a high-risk outcome decision

- Appreciated the value iQAAPS would bring to oversight for their trust and regional colleagues
- Using iQAAPS helped move the unit's cultural position on audit completion to a more digital and transparent place
- iQAAPS action plans and activities helped to escalate risks and issues to senior colleagues in the trust
- iQAAPS increased the importance of quality assurance in the trust

Case study 2 (typology 2: iQAAPS of limited value and low capacity to audit)

The context

Most recent iQAAPS audit: 2022

Unit capacity profile

- Workforce: Small (~7WTE)
- Facility: Large (~3 clean air devices)
- In-house production: Large (~90%)
- Total production: Small (~5,000 production)

Survey response

- Overall value of iQAAPS (mean score): 2 (max 10)
- Value of audit action plans (predominant rating): Unsure
- iQAAPS provides oversight (predominant rating): Unsure

The perceived value of iQAAPS in the context of a high-risk outcome decision

- Consistent negativity toward iQAAPS
- Some resistance to cultural change in audit processes
- Dissatisfaction with some of the training provided
- Delays between training and using iQAAPS in an audit for the first time made operationalisation difficult
- Reported difficulties finding time and space to upskill staff

The experience of managing the actions from a high-risk outcome decision

- Very challenging to delegate iQAAPS actions to other staff due to licence restrictions and functionality
- Needed to use a companion Excel spreadsheet alongside iQAAPS to manage the 50+ actions and staff allocated to support the actions
- Needed to develop a Word document to list the actions and responses and then upload to iQAAPS afterwards

The perceived impact of iQAAPS in the context of a high-risk outcome decision

- iQAAPS is a positive step away from previous report writing styles that were slightly more subjective and/or narrative
- There is a considerable volume of activities linked to multiple post-audit actions, e.g. email reminders, delegated actions, responses to auditors
- Stress levels were high among unit staff managing post-audit actions

Case study 3 (typology 3: iQAAPS valued and have capacity to audit)

The context

Most recent iQAAPS audit: 2022

Unit capacity profile

- Workforce: Large (~26WTE)
- Facility: Large (~7 clean air devices)
- In-house production: Small (~35%)
- Total production: Large (~18,000 production)

Survey response

- Overall value of iQAAPS (mean score): 6 (max 10)
- Value of audit action plans (predominant rating): Unsure
- iQAAPS provides oversight (predominant rating): Agree

The perceived value of iQAAPS in the context of a high-risk outcome decision

- Appreciated the factual, structured, and transparent approach of iQAAPS
- High levels of engagement between SPS and this unit were reported and may have facilitated the positive views
- Training was reported as adequate for their needs

The experience of managing the actions from a high-risk outcome decision

- Used a companion Excel spreadsheet alongside iQAAPS to manage the 90+ actions and staff allocated to support the actions
- Had to delegate many actions to different staff but this was hindered by the number of licences available and functionality to view others' completed actions

The perceived impact of iQAAPS in the context of a high-risk outcome decision

- There is a considerable volume of activities linked to multiple post-audit actions, e.g. email reminders, delegated actions, responses to auditors
- Appreciated the value iQAAPS would bring to oversight for their trust and regional colleagues
- iQAAPS action plans and activities helped to escalate risks and issues to senior colleagues in the trust

Case study 4 (typology 3: iQAAPS valued and have capacity to audit)

The context

Most recent iQAAPS audit: 2022

Unit capacity profile

- Workforce: Large (~23WTE)
- Facility: Small (~3 clean air devices)
- In-house production: Large (~60%)
- Total production: Large (~30,000 production)

Survey response

- Overall value of iQAAPS (mean score): 7 (max 10)
  Value of audit action plans (predominant rating): Unsure
  iQAAPS provides oversight (predominant rating): Agree

The perceived value of iQAAPS in the context of a high-risk outcome decision

- Appreciated the factual, structured, and transparent approach of iQAAPS
- Needed to encourage all unit staff to read the iQAAPS guides to ensure appropriate and efficient use of the platform
- High levels of engagement between SPS and this unit were reported and may have facilitated the positive views
- Training was reported as adequate for their needs

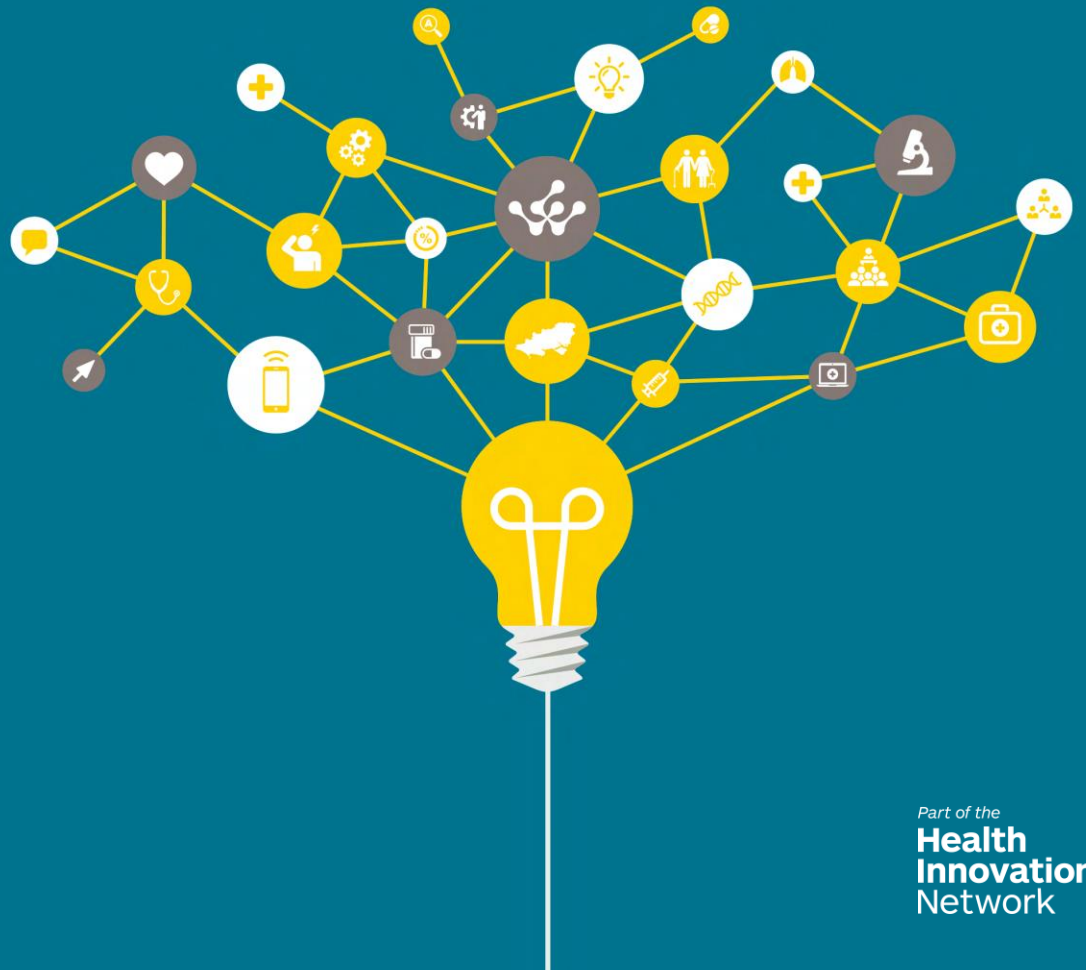
The experience of managing the actions from a high-risk outcome decision

- Used a companion Excel spreadsheet alongside iQAAPS to manage the 85+ actions and staff allocated to support the actions
- Had to delegate many actions to different staff but this was hindered by the number of licences available and functionality to view others' completed actions
- Needed to develop a Word document to list the actions and responses and then upload to iQAAPS afterwards

The perceived impact of iQAAPS in the context of a high-risk outcome decision

- There is a considerable volume of activities linked to multiple post-audit actions, e.g. email reminders, delegated actions, responses to auditors
- Appreciated the value iQAAPS would bring to oversight for their trust and regional colleagues
- iQAAPS action plans and activities helped to escalate risks and issues to senior colleagues in the trust

Conclusions



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Conclusions

Acceptability (Evaluation Question 1)

- When considering iQAAPS as a complete package, the mean score of all respondents (6.0, maximum of 10) indicated a moderate level of acceptability. However, considerable variation in views about the value of iQAAPS were apparent. At a high level, 'a tale of three cities' (auditors, unit staff and Chief Pharmacists) was identified – with Chief Pharmacists consistently more positive about iQAAPS.

- Regional variation in views about the value of iQAAPS was apparent. A sustained positivity toward iQAAPS was observed in Wales and the South West region and their acceptability increased with experience of iQAAPS. The case studies hinted that higher levels of engagement between SPS and these regions may have facilitated the positive views. Wales had the opportunity to pilot iQAAPS platform prior to its launch in England and it is possible that their aseptic units and auditors had more time to use and accept the changes in auditing process. In the North East region, there was consistent negativity toward iQAAPS and their acceptability decreased as they used iQAAPS in more audit cycles. The case studies indicated some resistance to change and using iQAAPS would involve a cultural change in operationalising audit activities. Tailored training and guidance may mitigate these variations in views.

- Staff at units with a high-risk audit outcome were more critical of iQAAPS. This was primarily due to the perceived burden of the situation, often having ~75 actions to operationalise, generating higher levels of communication within the unit and with the auditor, generating multiple actions plans, and working under greater scrutiny by their trust – all within the post-audit timeframe. iQAAPS provides a more robust audit and this generates more activity for unit staff, which is particularly exacerbated in high-risk units.

- Units with small in-house production capacity trend toward more positive sentiment compared to units with large in-house capacity. Although interesting to consider the capacity of units, our analysis is an interpretation of how capacity could be assessed and findings should be used with caution.

Conclusions

Enacting an iQAAPS audit (Evaluation Question 2)

- Despite iQAAPS not being designed to reduce workload, but to standardise audit activities for improved oversight and audit quality, 27% of all survey respondents agreed (strongly agree and agree combined) that workload to complete an audit had in fact reduced. For Chief Pharmacists, 38% agreed workload has reduced. This indicated there were efficiencies possible from using iQAAPS for some units.
- 44% of respondents reported a lack of sufficient training time to feel competent in using iQAAPS, but 64% knew to contact the developer for assistance.
- System access, logging in, editing, and uploading documents, were adequate but with some concerns about navigating the wide range of functions and routes to platform areas, and exporting information for reporting needs.
- It was noted there were multiple references to unit staff not reading the iQAAPS guidance, or engaging fully, or having an expectation that the tool would be simple/intuitive to use. Due to the complexity of the iQAAPS audit and thus the tool to manage the 16 chapters of ~100 standards, there is a responsibility on unit staff to actively engage with iQAAPS and its use.

Conclusions

Oversight and assurance (Evaluation Question 3)

- iQAAPS provided the anticipated enhanced oversight and assurance of aseptic units – with 68% reporting iQAAPS improved hospital-level oversight of aseptic unit activities and 64% stating iQAAPS provides a national view of performance.

- The added value of enhanced oversight was apparent as the majority (50%) of respondents stated iQAAPS supports improved hospital-level risk management of unit activities and the majority (41%) stated iQAAPS supports an improved ability to appropriately escalate identified unit risks.

Audit quality (Evaluation Question 4)

- iQAAPS helps to meet the quality standards of the aseptic pharmacy service (61%), improve the audit trail (63%), improve the quality of audit assessment (39%), and increase awareness of quality assurance (44%).

Action plans (Evaluation Question 5)

- Most staff (61%) stated audit action plans were valuable. This was lower in North East & Yorkshire (33%) region and high-risk units (17%). Case study findings indicate the former was related to dissatisfaction with training provided and delays between training and using iQAAPS in an audit. Case study findings indicate the latter was related to high volume (could be ~75) of deficiencies and related actions plans.

- Most staff (60%) stated iQAAPS helped communications with auditors and keep track (51%) of action plans. Respondents reported increased audit quality, transparency, assurance and time saved was facilitated by iQAAPS. However, concerns were raised about the inability to easily share action plans with senior colleagues.

Conclusions

Wider impacts (Evaluation Question 6)

- A wider impact was an increased awareness of quality assurance, reported by 44% of respondents. Sub-analyses indicated 75% of Chief Pharmacists agreed as did 67% of staff in the South West region.
- There were also indications iQAAPS outputs and insights were being used in the development of trust-level business plans.

Using iQAAPS in other areas of pharmacy and health services (Evaluation Question 7)

- Over half (55%) of respondents reported the iQAAPS auditing tool could be useful in other areas of pharmacy or healthcare services. Suggestions from Chief Pharmacists included pathology and blood science services that operate to very specific standards and key performance indicators. Also, training and education credentialing, General Pharmaceutical Council (GPhC) inspections, Royal Pharmaceutical Society (RPS) hospital pharmacy standards self-inspection, Wholesale Dealer's Licence (WDL) self-inspection, Home Office Controlled Drugs Licence inspection, CQC Regulation 12 self-assessment, and management of Wholesale Dealer's Licence in procurement.

Improvements to iQAAPS (Evaluation Question 8)

- A range of suggested improvements were made in three areas: tool development, training, and implementation. A combination of QuiqSolutions and SPS support would be needed to operationalise the suggestions.

Implications

1. **For QuiqSolutions:** A range of functional tool development suggestions were identified to mitigate frustrations held by unit staff and auditors. Whilst many are minor, the cumulative effect of their existence - accompanied by the stress and additional activities to manage audit action plans - affect the acceptability of iQAAPS.

2. **For QuiqSolutions:** Permitting an audit to be completed in real time, e.g. via an iPad with an intuitive interface, was a common view of auditors. This would speed up the auditor's activity at units and potentially increase the volume of audits conducted. It was acknowledged this is possible and no technical resolutions are needed, but it would be beneficial if training were provided on how to make the best use of iQAAPS when using it in real-time during a visit.

3. **For QuiqSolutions:** Further development and tailoring of training tools for this complex digital innovation would be welcomed by many respondents. The findings from this evaluation would suggest the need for regional / contextual tailoring of iQAAPS training, e.g. focusing more on the rationale and value of IQAAPS in some regions, focusing on management of multiple deficiencies and action plans in high-risk units, and different training for units with high/low workforce capacity.

4. **For QuiqSolutions:** Guidance on the use of iQAAPS exists for auditors and unit staff but not for Chief Pharmacists. Whilst Chief Pharmacists were generally very positive, guidance to support their senior stakeholder role in managing and sharing iQAAPS information may increase their positivity further. Also, such guidance may include how to support unit staff when managing a high number of deficiencies and action plans, or when previous ways of working are affecting the use of iQAAPS.

5. **For Specialist Pharmacy Service / auditors:** Due to the importance and thorough nature of iQAAPS audits, using iQAAPS is a complex digital innovation to train to use and manage - particularly when responding to a high-risk audit outcome. Additional support and time would potentially help units with a high-risk outcome.

Implications

6. **For Specialist Pharmacy Service / auditors:** To maximise the benefits and minimise the limitations of iQAAPS, the findings suggest unit staff training processes should be rigourous and ensure internalisation of iQAAPS guidance. Emphasising the need, benefits, and mitigations of the limitations may ensure higher acceptability and smoother implementation.

7. **For Specialist Pharmacy Service / auditors:** whilst training support exists from QuiqSolutions, this is understandably focused on functional elements. SPS and auditors could consider developing an online training support network to support unit staff with fitting in iQAAPS activities into their existing activities and identifying interdependencies that affect its use.

8. **For unit staff:** Due to the complexity of the audit, using iQAAPS takes time to learn. There is a responsibility on unit staff to engage with the available training and guidance and seek support where available.

9. **For unit staff:** iQAAPS is new and has some limitations. Sharing the experience of unit staff with the developer and SPS would greatly benefit the audit tool and support more efficient audits in the future.

10. **For unit staff:** High variation in views about iQAAPS were identified, particularly in different regions and units with different outcome statuses. Reflecting on why iQAAPS has not been viewed as satisfactory within your unit would benefit unit staff.

11. **For unit staff:** Consider the most effective bundle of tools to efficiently complete an audit. If additional spreadsheets are needed to manage the audit alongside iQAAPS, share these with other units or investigate if they exist.

Implications

12. **For Chief Pharmacists:** iQAAPS was highly valued for its enhanced oversight and increased rigour, but this meant increased audit activity for unit staff. To sustain the welcome levels of oversight and rigour, it may be necessary to increase the number of staff / time granted to support iQAAPS audits.

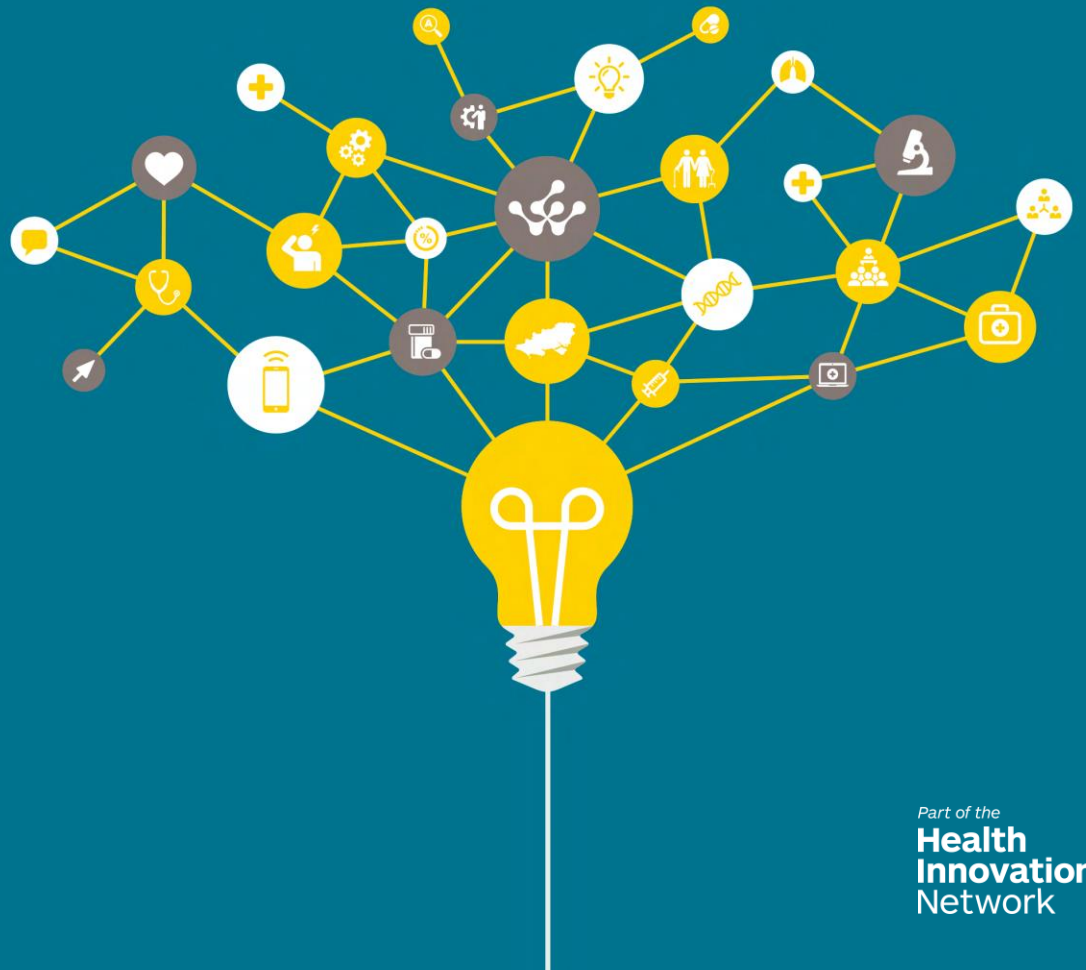
13. **For Chief Pharmacists:** Special considerations are likely needed when units receive a high-risk outcome and use iQAAPS to manage the action plans. Managing unit capacity and learning from other units may support unit staff to realise the benefits of iQAAPS.

14. **For Chief Pharmacists:** iQAAPS has helped raise the profile of quality assurance and this could be used to develop a pool of staff to support the Accountable Pharmacist to manage the iQAAPS actions and processes. It may also help to ensure appropriate resources are available to manage post-audit actions.

15. **For Chief Pharmacists:** iQAAPS has potential uses in related areas, e.g. GPhC and RPS inspections. Exploring how the platform can be adapted for other uses may be an efficient way to optimise time already spent by unit staff learning to use iQAAPS.

16. **For NHS Executives:** the iQAAPS platform could be transformed and used in other parts of the NHS for auditing purposes, e.g. pathology, blood science services, and processes related to the human tissue authority.

Potential improvements



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Suggested improvements – iQAAPS functionality

1. All respondent types indicated an ability to customise the dashboard to add or remove sections relevant to the viewer would be helpful. Or develop three different platform views for unit staff, auditors, and Chief Pharmacists. E.g. for auditors, the platform does not show a tally of the number of deficiencies. Also, respondents stated there is an inability to look at the standards, the deficiency and the action plan in the same field of vision. This makes checking the action plan very time consuming and can lead to errors.

2. Chief Pharmacists indicated they need an improved action planning section, and clarity between audit actions and self-assessment action, with target dates, responsibility and update. However, shortly after data collection was completed, changes have been made to the platform to improve the action planning section.

3. Chief Pharmacists indicated they need an easier way to understand the information iQAAPS holds, how to navigate to it, and share outputs it in a format that doesn't need additional work.

4. Auditors indicated innovative methods such as making and sharing videos (both unit staff and auditors) would be beneficial to the efficiency of audit process.

5. Auditors indicated they cannot register comment or give advice in the platform, only reply factually to each standard. However, shortly after data collection was completed, changes have been made to the platform to improve this issue.

6. Auditors indicated there are time consuming aspects to iQAAPS. There isn't a way of navigating efficiently to the required standard. The in-built search function appears under used. When writing the summary of a chapter the comments cannot be seen or copied without coming back out of the summary and back into the comment to copy text, it can take ten seconds to move between fields. Also, it isn't possible to upload multiple documents related to the same point at one time.

7. Auditors and unit staff indicated an undo function and autosave function would help reduce 'clicks' and time conducting the audit. It's also possible to accidently click outside a standard text box and lose all content written within it.

Suggested improvements – Implementation of iQAAPS

1. Consider tailoring licence access to match the unit capacity and/or level of deficiencies and action plans a unit must enact. The limitation of five funded licences to use iQAAPS per unit can hinder audit completion. High-risk units may need more staff to support the wide range of post-actions. In some cases, only the Accountable Pharmacist could complete the audit. When they were on annual leave, no other members of the team could upload data to iQAAPS.

2. Develop functions to support unit staff coordination. Only the person marked as owner of action plans can review and edit them. The Accountable Pharmacist must be the owner of the action plan(s) and subsequently the rest of the team members that have a licence to access iQAAPS can only access the actions that apply to them instead of the whole. It was not possible to directly export and share the action plan with the wider team, however, since data collection was completed this issue has been addressed by the developer.

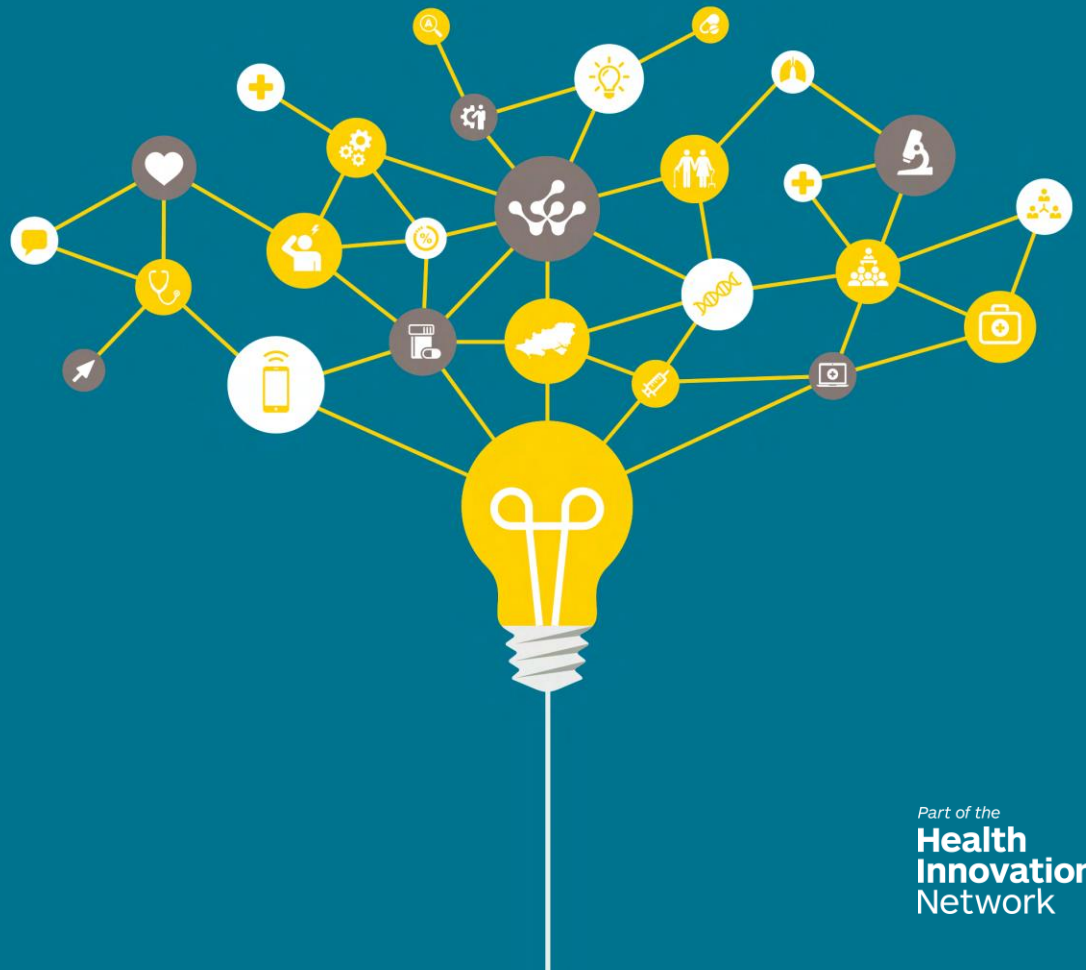
3. Develop a team sign-off function. Individual licence users cannot see when other licensees have completed their actions. This creates challenges for sign-off of actions by the Accountable Pharmacist at a unit, however, since data collection was completed this issue has been addressed by the developer.

4. Develop a broader range of training videos (suggest inviting staff using iQAAPS to make the short videos, so they can describe the experience in the right context and language) to support these situations: different role types (Chief Pharmacists, auditors, unit staff) and different risk ratings (low, medium, high). A focus on the necessity, any predictable concerns, and value of iQAAPS in each situation would be beneficial.

5. Develop a training video about the value and concerns of iQAAPS to acknowledge it exists to drive up audit quality and oversight, but has the knock-on effect of requiring active engagement by unit staff to become familiar with the platform and adjust their ways of working.

6. Different training formats, e.g. videos with audio, Microsoft Teams-based, and face-to-face sessions were requested by respondents.

Appendices



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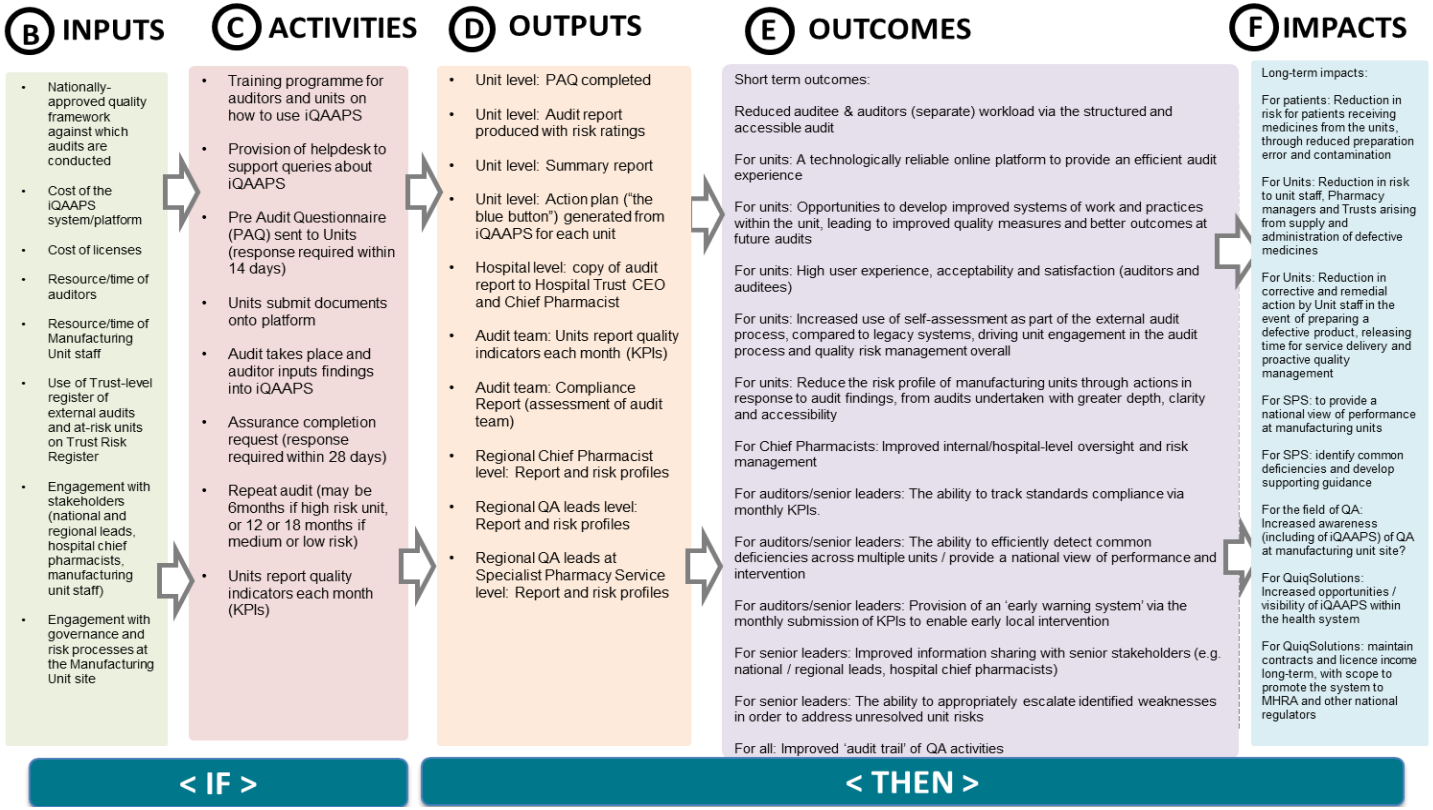
Appendix A: iQAAPS logic model guiding the evaluation

Context: iQAAPS, developed by Quiqsolutions, is an electronic audit tool developed in partnership with the Specialist Pharmacy Service (SPS) to support external audits of NHS Pharmacy Aseptic Units



Appendix B: Definitions of capacity variables

Some sections of the pre-audit questionnaire, for units who responded to the surveys, were obtained from the evaluation client. Several capacity-related variables were created to support the analyses:

Workforce capacity was determined from the total whole time equivalent reported by the unit. Small workforce (<15, n=16), large workforce (≥15, n=23) [missing data, n=3]

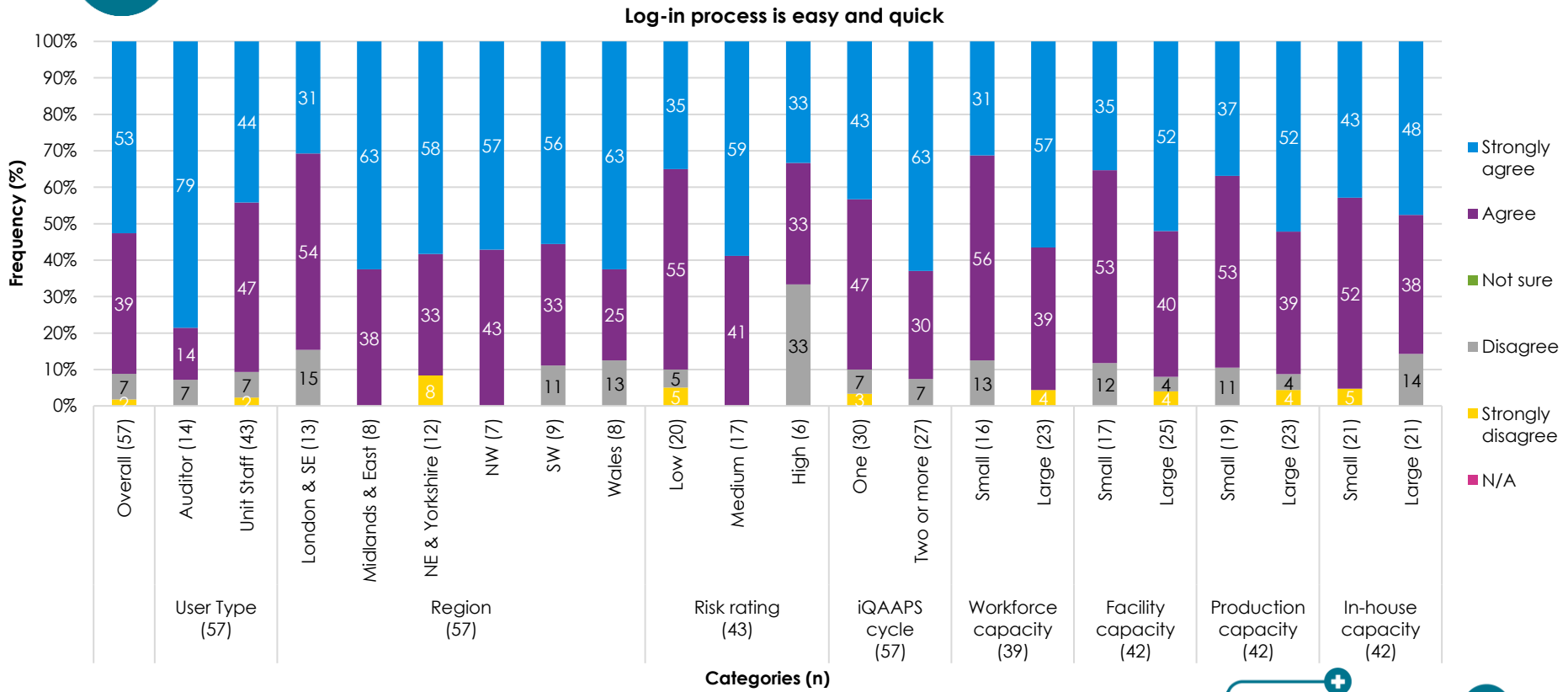
Facility capacity was determined by the number of available clean air device reported by the unit. Small Facility Capacity (<4, n=17), Large Facility Capacity (≥4, n=25)

Production capacity was determined by the reported total number of aseptic pharmacy production (including production under the Medicines Act 1968 Section 10, Manufacturer's 'Specials' Licence [MS Licence] and outsourced production). Small Volume (<20,000, n=19), Large Capacity (≥20,000, n=23)

In-house capacity was determined by the percentage of production under Section 10 and MS licence against the unit's total production. The level of capacities were divided into either large or small capacity. Low Capacity (<80%, n=21), High Capacity (≥80%, n=21)

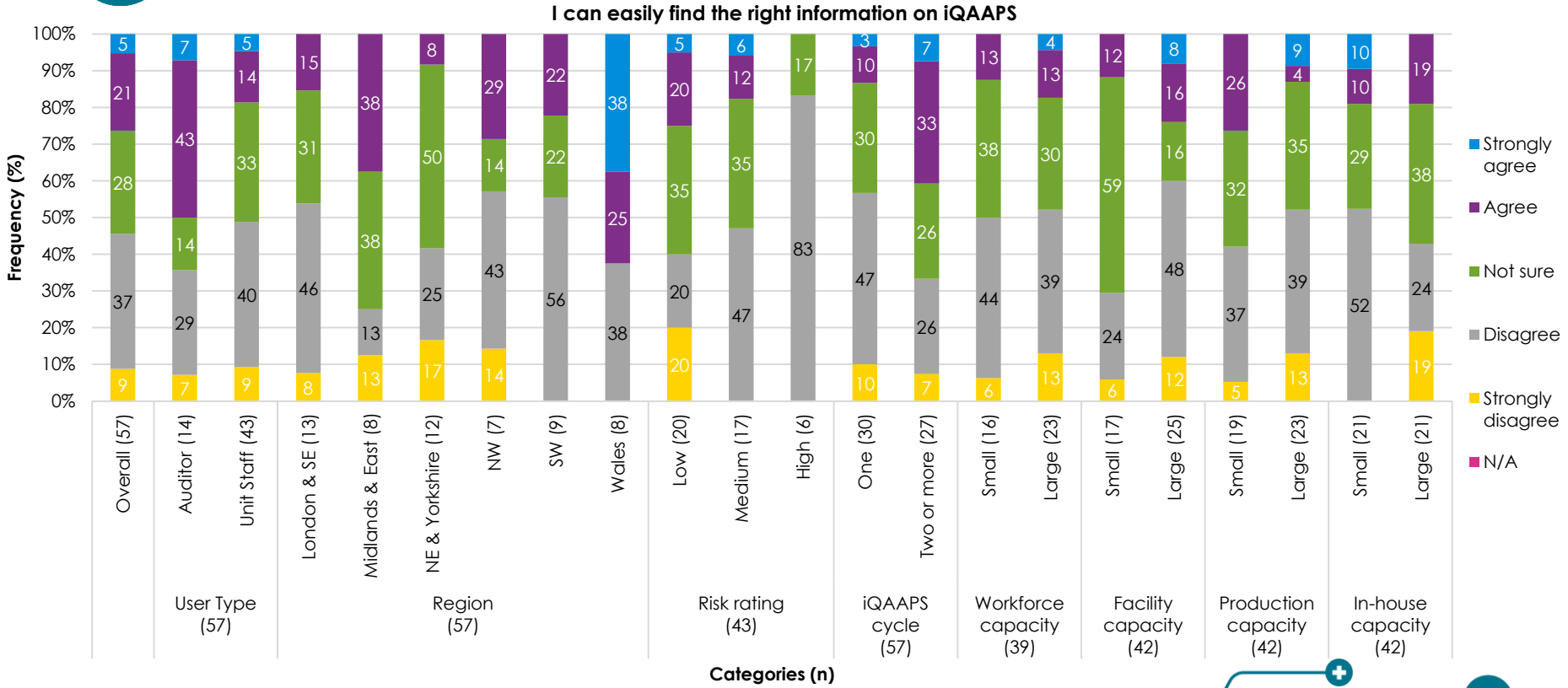
The cut-off values to determine whether a unit has high or small capacity in these four domains were determined by the available pre-audit questionnaire data. Method of establishing the cut-off values for each domain involved calculating the central tendencies (mean, mode and median) and frequency distribution of each variables to determine appropriate point to separate data range. Once the cut-off values were measured, the evaluation client was consulted to ensure the cut-off values were reflective of real-life perception of unit capacities.

Appendix C: Views on system access



Abbreviations: N/A = Not Applicable; NE = North East; NW = North West; SE = South East; SW = South West.

Views on system access



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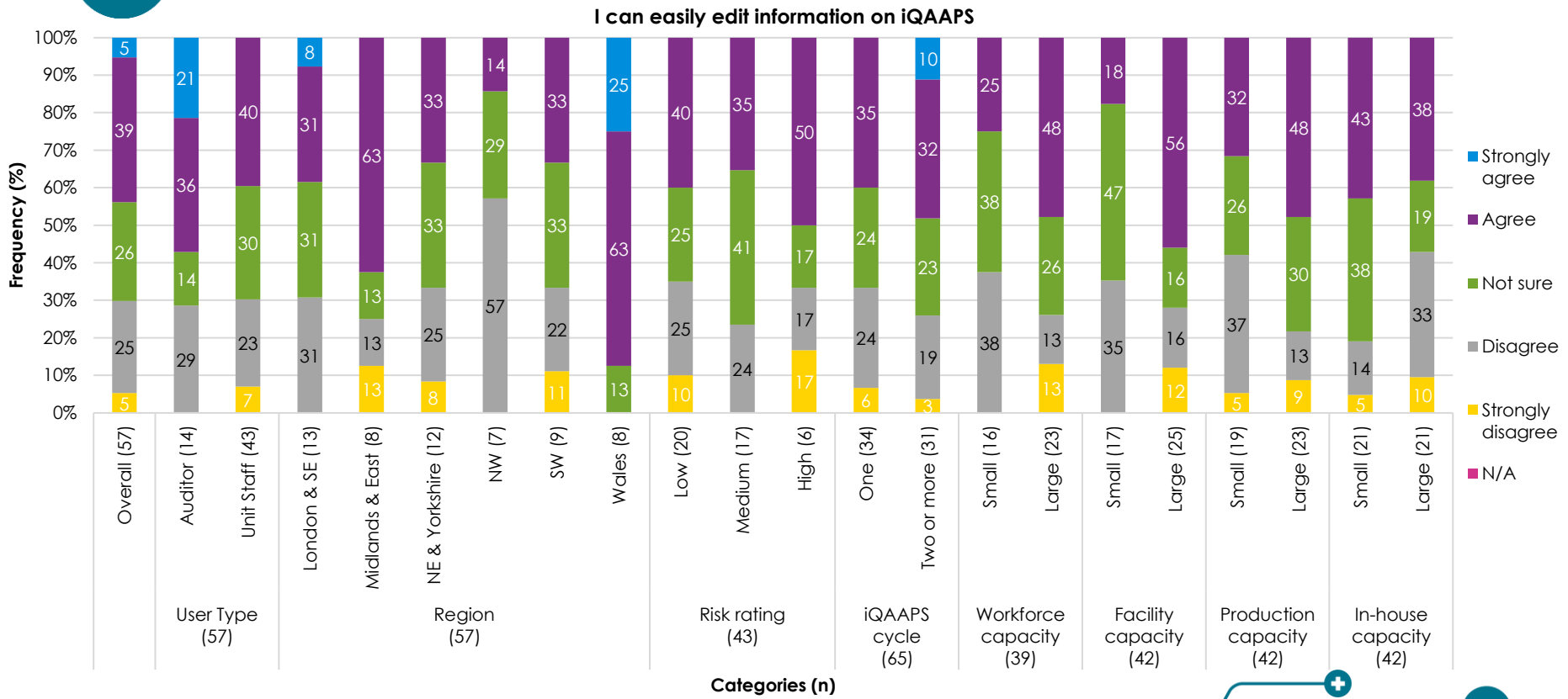

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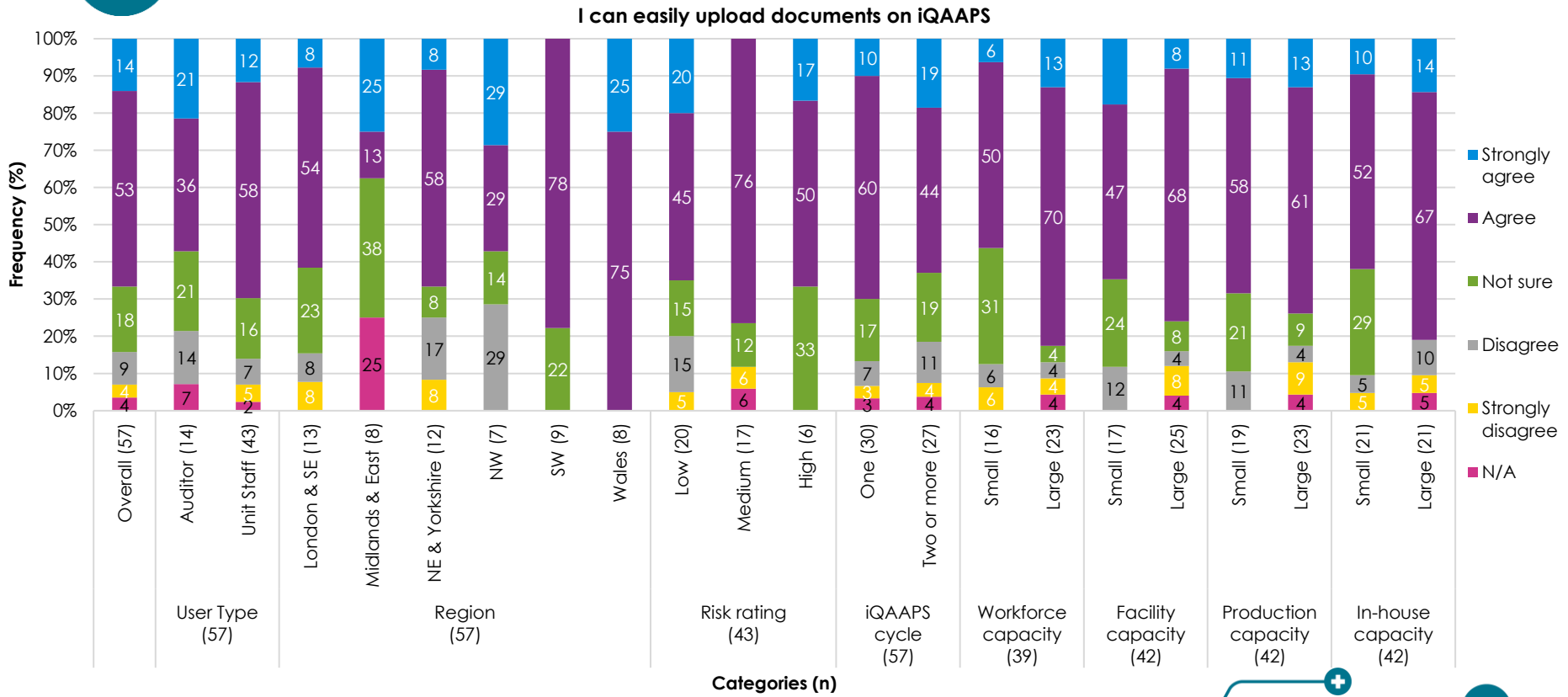

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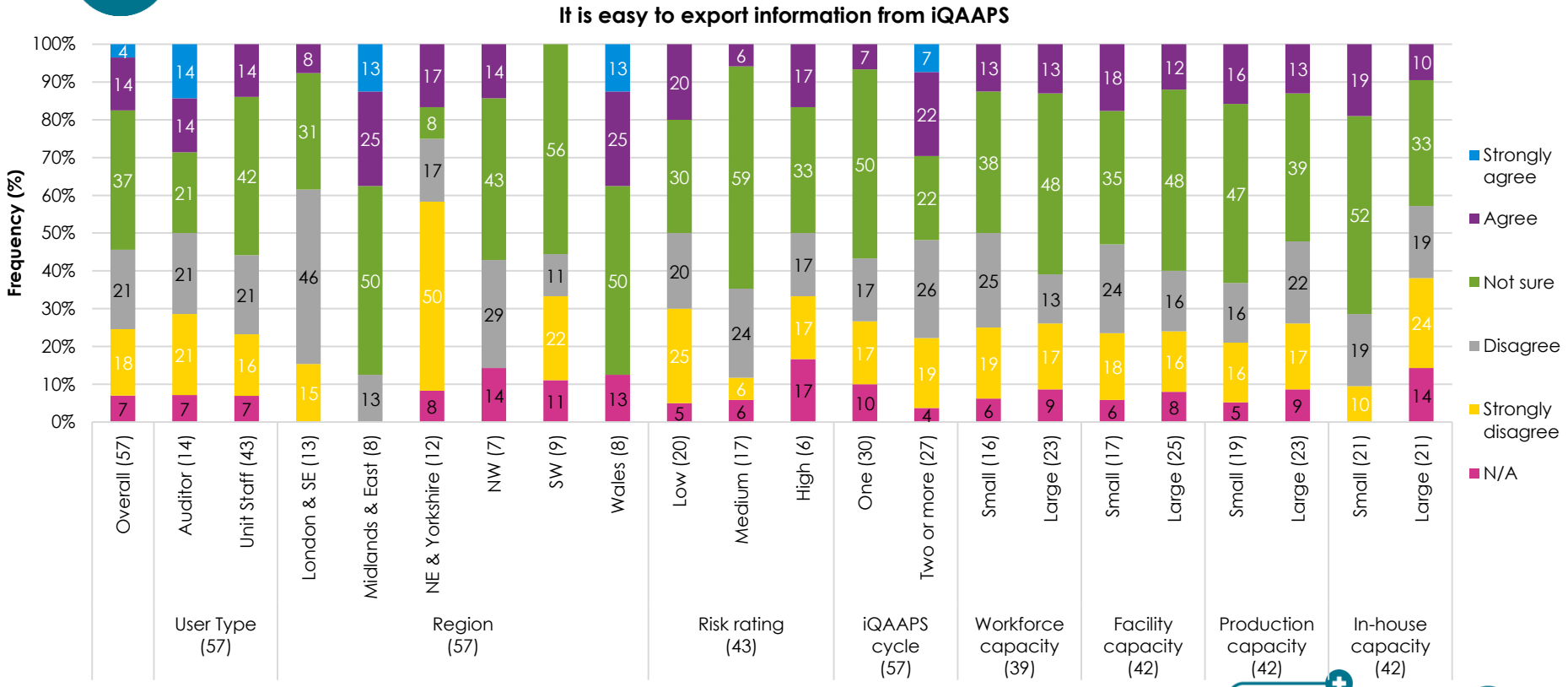

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