



The QA and Technical Services Interest Group of the
Guild of Healthcare Pharmacists

Pharmaceutical Quality Assurance and Technical Services Symposium 2023

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POSTER APPLICATION FORM

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Poster title	Risk Assessment and Handling Practices for Monoclonal Antibody Practices: A National Review

Please submit details of abstract overleaf

Please note: all poster applications must be submitted by 18th August 2023

Please return your application to:

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marking the subject as "Symposium Posters"

ABSTRACT

Risk Assessment and Handling Practices for Monoclonal Antibody Practices: A National Review

- The aim of this research was to understand how institutions are risk assessing and handling monoclonal antibodies in the UK.
- The results showed there was variation of how these products were handled and risk assessed including some deficiencies on available documentation and PPE provision
- Using the research results a set of recommendations were devised and used to create a risk assessment process with corresponding flow chart and clinical area checklists.

Aims

The aim of this study was to establish how monoclonal antibody products are handled, prepared and risk assessed within UK healthcare settings, with a focus on who, where and how these products are being made and the factors that influence these decisions. This was used to provide recommendations for improvement where necessary.

Methods

The study consisted of two phases. Phase one included an electronic survey consisting of 35 questions circulated via participating professional networks. Questions focused on demographics, handling procedures, attitudes to risk, institutional procedures, risk assessment and risk reduction measures. Phase two of the study was semi-structured interviews that were used to gain greater insight into institutional practices or clarify ambiguous survey results. Non-linear analysis and general inductive methods were used for trend analysis.

Results

The survey showed that institutions are preparing monoclonal antibodies in pharmacies and a range of ward-based areas. The preparation is most commonly undertaken by pharmacy staff and registered nurses. Where ward-based preparation is undertaken it is sometimes done without the recommended PPE and without available preparation guidelines. Training programs for staff preparing monoclonal antibodies may be lacking and this has led to knowledge gaps within staff grades.

Conclusions

There has been much discussion on the occupational safety of monoclonal antibodies (1) since their introduction with several risk assessment methodologies put forward (2,3). However there has never been a UK wide review of the implementation of these processes. This research shows there are many factors that affect the decision process regarding where monoclonal antibodies can be made, extending beyond the health and safety considerations of staff. These risk assessment methods sometimes lack prescriptive risk reduction methods leading to the development of the guidelines and methodology put forward in this project

1 Alexander M, King J, Bajel A, Doecke C, Fox P, Lingaratnam S, Mellor JD et al. Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel. *Intern Med J*. 2014; 10:1018-26. doi: 10.1111/imj.12564

2 Langford S, Fradgley S, Evans M, et al. Assessing the risk of handling monoclonal antibodies. *Hosp Pharm* 2008; 15: 60–64.

3 Bauters T, Vandenbroucke J. Development of a flowchart for risk assessment and allocation of preparation of monoclonal antibodies. *J Oncol PharmPract*. 2019;25(1):187-191. doi:[10.1177/1078155217743095](https://doi.org/10.1177/1078155217743095)

