ICGP Short Guide to Audit

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Background

Part 11 of The Medical Practitioners Act 2007 is the foundation of the professional competence system which places a legal duty on doctors to maintain their professional competence by following requirements set by the Medical Council. This came into effect in May 2011 and as a result it is now obligatory for every practicing GP to conduct at least one audit per year, in order to comply with the requirements of competence assurance. This brief guide is written to help you conduct an audit in your practice that will help meet these requirements.

What is clinical audit?

Audit is a quality improvement process, which seeks to determine if we are doing what we should be doing, and the findings are intended for use at a local (practice) level. In the Medical Council's Professional Competence guidance booklet, clinical audit is defined as the "systematic review and evaluation of current practice with reference to research based standards [and designed] to improve patient care". The setting of standards, the measurement of practice compared to a 'gold standard', the identification of deficiencies and addressing deficiencies (closing the loop) are the accepted components of clinical audit.

The Medical Council rules (published on January 18th, 2011) specify however that "Audit activities should be focused on the practice of the practitioner and not on the processes". For example in an audit of diabetes, review HbA1c levels rather than simply whether a blood test for HbA1c has been taken. In some audits, it will be necessary or preferable to include some process elements so these do not have to be excluded; however, the entire audit cannot be based around processes for the purpose of fulfilling your professional competence requirements.

Clinical audit has three elements:

1. Measurement – measuring a specific element of clinical practice

2. Comparison – comparing results with the recognized standard/guideline

3. Evaluation – reflecting on outcome of audit and where indicated, changing practice accordingly.

How to carry out an audit

The steps involved are[1]:

1. Decide on your topic
2. Define your Aims and Objectives and reason for undertaking this audit
3. Choose your Guidelines
4. Select your Criteria from the guidelines chosen [*Note the criteria are elements of care or activity, which can be measured*]
5. Set your Standard *[Note your standard (sometimes known as your target) is your desired level of performance and is usually stated as a percentage]*
6. Collect, Analyze and Interpret the relevant data from your patients/practice
7. Decide on what changes need to be made and implement them
8. After a reasonable timeframe, re-collect data and analyze it to ensure an improvement has occurred.

The report from your audit may be anything from two pages in length but should contain the following information[2]:

1. Reason for the audit
2. Criterion or criteria to be measured
3. Standard(s) set
4. Description of the preparation and planning
5. Results of the initial data collection
6. Description of change(s) implemented
7. Results of the data collection post changes
8. Conclusions.

Keeping your audit projects relevant to your practice, short, simple and easily manageable is the key to success. Choosing a topic is the first step and there should

be agreement within the practice that the chosen topic for audit is a worthwhile area to study**.**

Ethical Considerations

Clinical audits usually involve looking at information already collected about a patient or treatment and do not usually involve gathering new information. In addition, the data is mainly gathered for internal (practice) consumption in one practice for the improvement of care/services in that practice and is completed by the caregiver or a member of his/her team. Hence, audit does not usually require ethical approval. Identifiable data should not be used – only anonymous data should be extracted/compiled for the audit.

However, if you intend to gather new data, to interview/test patients, to permit access to files to an individual not in your employ, to transfer non-anonymous data outside the practice or to use the data for research, you should obtain additional advice regarding the ethical review requirements.

Data Protection Considerations

GDPR is the EU's new General Data Protection Regulation (EU) 2016/679. It came into force across all of Europe on 25th May 2018[3]. It replaced the EU's previous Data Protection Directive (95/46/EC). GDPR governs the collection, use and storage of all personal data of living individuals. The Data Protection Act 2018[4] is the Irish legislation that gives effect to certain aspects of the EU's GDPR in Ireland and repeals, for the most part, the previous Data Protection Acts 1998 and 2013. As you collect, use or store personal data in digital, manual, handwritten or any type of record, then GDPR affects you. The suitable and specific measures for data processing provided for in Section 36 of the draft Data Protection Act 2018 are given further and more specific effect through the Health Research Regulations 2018 (formally titled Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018)[5]. While the Department has indicated that it will publish similar in relation to audit, it should be noted that these health research regulations relate to research and not to audit.

Given these changes, the Medical Council has published advice[6] in relation to conducting your audit.

In summary, during a clinical/practice audit, health data is processed and the process of data retrieval/extraction from the patient record in itself amounts to processing. However, such data can be processed in situations where is it necessary to do so for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of healthcare (Article 9(2) of the GDPR)[3]. Hence, you can lawfully process special category data for the purposes of clinical/practice audit, however you must ensure that you adopt suitable and specific measures to safeguard the fundamental rights and freedoms of the data subjects concerned. You, therefore, are not required to seek consent before processing special category data for the purposes of undertaking a clinical/practice audit once you ensure that you are compliant with the transparency obligation in the GDPR Article 5(1)(a)[3] by ensuring that comprehensive privacy notices are provided to your patients.

It is important to inform patients that the practice may use data for internal audit with an option for them to opt out of this use of their data. This can be included in a patient information leaflet or a privacy statement. It is not acceptable for external research staff to trawl through individual patient records without informed patient consent. It is also not acceptable to release the contact details of patients to researchers without informed patient consent. Only anonymized data should be used.

Registering your Audit

The facility to record your audit activity is contained within your Professional Competence ePortfolio on www.icgp.ie. This asks you to record the audit title, start date, end date and a brief description. You can also upload supporting documents, for example, the report. Uploading supporting documents is optional but will facilitate review and validation, should you be selected for same.

Audit Examples

There are of course many possible audit topics within general practice. Some suggested topics with sample criteria are provided in the ICGP audit toolkit along with fully worked examples of the following to demonstrate what is required.

Example 1: Management of Adult Coeliac Disease.

Criteria to be measured: The criteria contained in the Primary Care Society for Gastroenterology in UK and the Clinical Resource Efficiency Support Team (CREST) in Northern Ireland regarding annual review.

Standards set: 40% of patients with coeliac disease should have an annual review.

Data collection tool:

Number of patients in practice	
Number of patients with coeliac disease	
Number of patients with coeliac disease with annual review documented	
Number of patients with coeliac disease with weight documented	
Number of patients with coeliac disease with DEXA scan completed	
Number of patients with coeliac disease with bloods checked in last 12 months	
Number of patients with coeliac disease with EMA checked for compliance	
Number of patients with coeliac disease who had been reviewed by a dietician	

Example 2: Seasonal influenza and pneumococcal immunization in diabetic patients.

Criteria to be measured: Patients with Diabetes Mellitus should have pneumococcal vaccination; Patients with Diabetes Mellitus should have influenza vaccination.

Standard(s) set: Pneumococcal vaccine will be offered to 100% of patients with Diabetes Mellitus; aim is to have an uptake rate of pneumococcal vaccine >95% in patients with Diabetes Mellitus. Annual influenza vaccine will be offered to 100% of patients with Diabetes Mellitus; aim is to have an uptake rate of influenza vaccine >95% in patients with Diabetes Mellitus.

Data collection tool:

No. of patients	Type 1	Type 2	Total
PPV vaccine given			
PPV vaccine not given			
PPV vaccine refused			
Flu vaccine given			
Flu vaccine not given			
Flu vaccine refused			

Example 3: Asthma Management in an Irish Suburban General Practice.

Criteria to be measured: A combination of guidelines was examined, but in particular the GINA guidelines as they are the gold standard for asthma care, and the ICGP guidelines, as they are a summary of the latter in an Irish context, were used. The criteria selected was in terms of the recommended annual review of asthma patients.

Standard(s) set: Asthmatics should be on a register (90%); Asthmatics should be reviewed in the last year (90%); Adult asthmatics should have their smoking status documented and if smoking should be given brief intervention for smoking cessation (70%); In asthmatics under 18 years, parents should be asked if there are any smokers in the house (70%); As part of the asthma review patients should have their inhaler technique checked and documented (50%); If asthmatics are under 18 they should have their height/weight and centiles documented (70%).

Data Collection tool:

	Children	Adults
Number of patients in the practice		
Number of asthmatics		
Number of asthmatic on register		
Number of asthmatics reviewed in last year		
Number with documented smoking status		
Number of children with smokers in the		

household		
Number with inhaler technique checked		
Number with centiles documented		

Further assistance

For elaboration on the steps above, audit examples/suggestions, audit template documents and answers to frequently asked questions, see the ICGP Audit Toolkit on www.icgp.ie

For any audit queries not answered in the audit toolkit, please email your question to professionalcompetence@icgp.ie. These will be used as the basis for a regular feature in Forum magazine and a Frequently Asked Questions section on the ICGP website. It may not be possible to answer all individual queries directly.

References

[1] United Bristol Healthcare. How do I carry out an audit. http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/

[2] Bowie P, Garvie A, McKay J. Ideas for Audit: A practical guide to audit and significant event analysis for general practitioners. NHS Education for Scotland. November 2004.

[3] General Data Protection Regulation (EU) 2016/679 http://data.europa.eu/eli/reg/2016/679/oj

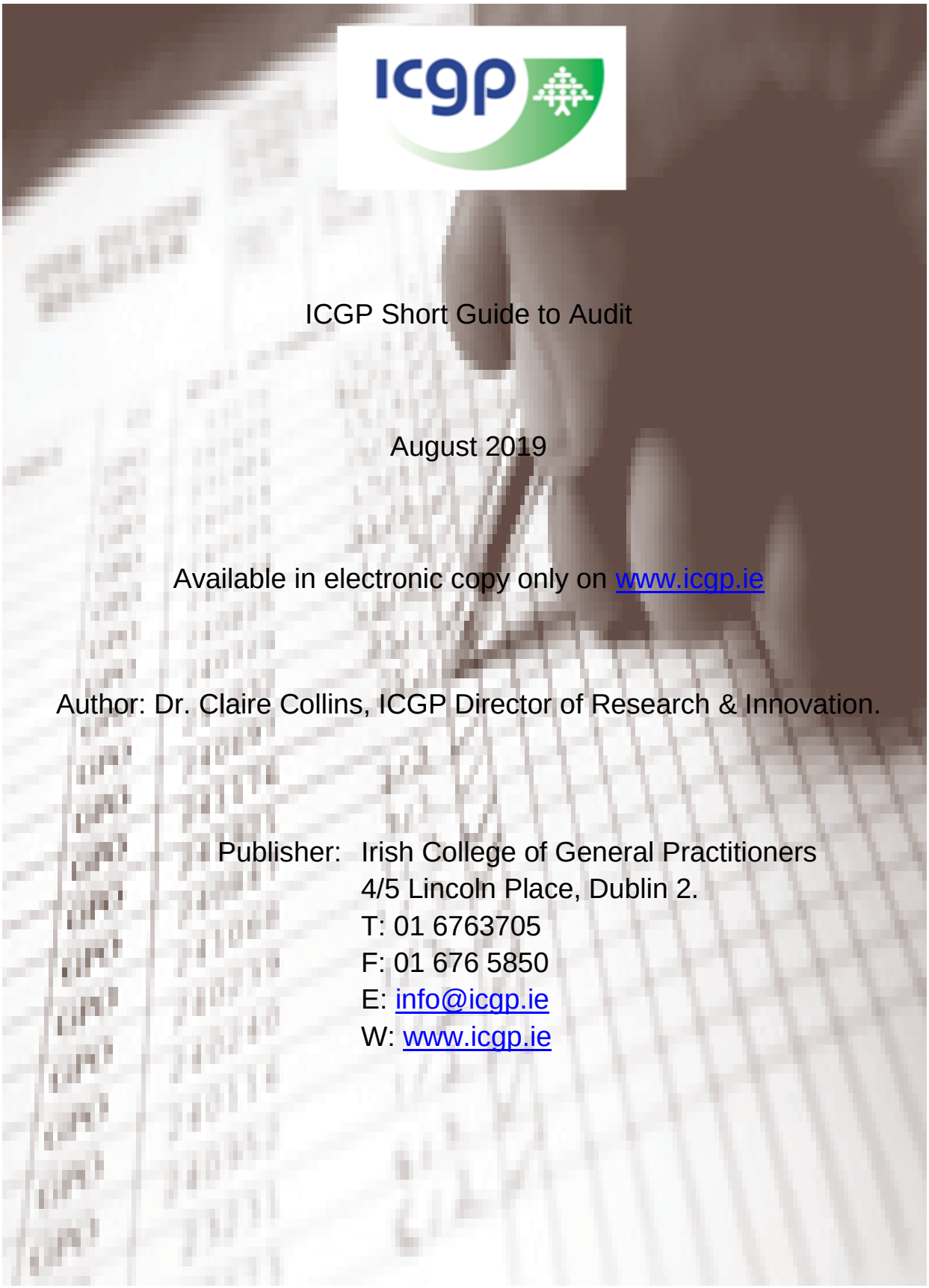
[4] Data Protection Act 2018 http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/pdf

[5] Health Research Regulations 2018 http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

[6] Irish Medical Council Guidelines on the implications of GDPR on Clinical Practice Audit 2019 https://www.medicalcouncil.ie/Existing-Registrants-/Professional-Competence/Guidelines-on-the-implications-of-GDPR-on-Clinical-Practice-Audit.html

Disclaimer

The contents of this document are intended as a guide only and although every effort has been made to ensure that the contents are correct, the ICGP or it agents cannot be held responsible for the outcome of any loss or damage that results from the use of this guide. It is accepted that other interpretations of the requirements for audit by the Medical Council may be possible in order for GPs to comply with their audit requirements under the terms of the Medical Practitioners Act 2007. This guidance is for educational and informational purposes only and should not be considered as legal advice.



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