



Strategic Programme for Primary Care

A Rapid Review of Clinical Governance, Quality & Safety in Primary Care in Wales

Executive Summary

Clinical Governance is an integral part of Primary Care and Community Services and has recently been added as a priority to the programme of work for the Strategic Programme for Primary Care for Wales. Health Boards (HBs) are individually responsible for ensuring the quality and safety of all services they deliver directly, and also for monitoring the services they contract from independent contractors.

A task and finish group (T&F), led by the National Clinical Lead for Primary Care, undertook a rapid review of Clinical Governance, Quality & Safety in Primary Care in Wales. It met five times and heard evidence, and academic reviews, from a wide variety of professional and managerial sources, from within the NHS in Wales and internationally.

The T&F group considered the following high levels recommendations;

- Clinical Governance in Primary Care in Wales does exist, but it is complex and variably assessed by HBs and providers. All 7 HBs need to adopt and implement a single strategic model that pulls all the strands together and organizes the complexity.
- A single multi-dimensional framework for quality assurance, based on the above model and Health Care standards for Wales, needs to be adopted and implemented by all 7 HBs for independent contractors.
- Some independent contract reform may be required to maximize effectiveness of clinical governance processes, but it is more important to use existing contractual levers when necessary.
- Systems, Processes and Pathways must be developed to support primary care clinicians to learn from others across Wales.
- Data needs to be shared and analysed by specialists at national level, and securely published at the appropriate level as part of everyday NHS processes, to reap the benefits of 'Big Data' in primary care.
- Existing data should be mined first where possible and should be from multiple sources.
- Patients and carers should co-produce clinical governance.
- Links between the NHS Primary Care and Research into Quality & Safety needed to be strengthened.
- Primary Care Medical Advisory Team's future needs further deliberation in the view of the proposed development of the model and assurance framework.

Based upon the above four key areas require consideration and supporting actions to address the issues.

- Creating an Overarching Clinical Governance Strategy for Primary Care in Wales
- Building a National Framework for Assurance
- Supporting Clinicians to Learn and Improve
- Developing the Tools to Enable Safe, Sustainable, Quality Care

1. Introduction

Clinical Governance is an integral part of Primary Care and Community Services and has recently been added as a priority to the programme of work for the Strategic Programme for Primary Care for Wales. Health Boards (HBs) are individually responsible for ensuring the quality and safety of all services they deliver directly, and also for monitoring the services they contract from independent contractors.

In August 2020, the Strategic Programme Board for Primary Care agreed for the National Clinical Lead for Primary Care to lead a rapid review of Clinical Governance in Primary Care in Wales. This paper outlines the discussions and recommendations of the task and finish group led by the National Clinical Lead.

The group was asked to consider a common approach across Wales for how quality and safety can be assessed with validity and reliability. The review also considers how a harmonised system of high value governance processes across the seven HBs would ensure General Medical Services (GMS) monitoring consistently identifies and acts upon quality and safety issues, both during COVID-19 and beyond. The review considers how individual practitioners can be supported and how learning from incidents or reports can be shared effectively at scale. Finally, it also considers how a harmonised system of high value governance processes across seven HBs' Performers Lists would ensure professional performance issues are consistently identified and acted upon.

Purpose

The Purpose of the review group was;

- a) To **review evidence** (as published literature, expert opinion and personal experience, including that of patient and carers), in the field of governance, quality and safety in primary care
- b) To briefly **review current arrangements in each HB for monitoring governance**, quality & safety in primary care, and comment on their effectiveness in supporting the Quadruple Aim
- c) To **describe principles for measurement** of quality and safety in primary care and community services in all 7 LHBs in Wales to support the Quadruple Aim.
- d) To **suggest metrics** based on the principles listed in c.
- e) To **describe any infrastructure or processes that would be needed to support** the use of these metrics when the data is to be used for
 - i. quality improvement
 - ii. quality assurance
 - iii. and/or research
- f) To **describe a national framework for monitoring governance in GMS contracts**
 - i. that can be used in all 7 LHBs
 - ii. that is valid and reliable in identifying quality and safety issues
 - iii. that can be used during the COVID-19 pandemic and beyond
 - iv. that is acceptable to professionals, patients and LHBs
- g) To **describe a national framework for monitoring and learning from management of medical and optometric professional performance concerns**
- h) To **advise on the future role of the Primary Care Medical Advisory Team (PMCAT)**

Task and Finish Group Members

An expert-led and task-orientated Task and Finish Group was established. AMDs from across all Health Boards were invited (and asked to send a deputy where unable to attend). Members included:

- Lead: Dr Alastair Reeves, National Clinical Lead, Strategic Programme for Primary Care
- PMO Support: Stacey Forde, Iris Wilmshurst, Kelly King
- Dr Anjula Mehta, Interim AMD SBUHB
- Dr Anne-Marie Eliades, Clinical Director ABUHB
- Dr Bethan Jones, Area MD (West), BCUHB
- Clare Evans, Head of Primary Care, C&V UHB
- Dr Clifford Jones, Clinical Director ABUHB
- Dr Fraser Campbell, AMD, BCUHB
- Dr Helen Kemp, HIW Clinical Lead for Primary Care and Clinical Director for Q&S at SBUHB
- Dr Jeremy Tuck, AMD, Powys Teaching Health Board
- Dr Jim McGuigan, Area MD (East), BCUHB
- Dr John Boulton, Improvement Cymru
- Dr Karen Gully, Clinical Director, ABUHB, & RCGP Wales /Cymru Quality Lead
- Dr Liz Bowen, Area Medical Director, BCUHB
- Dr Mark Walker, SMO Primary Care, Welsh Government
- Dr Nicky Davies, Assistant MD (Central), BCUHB
- Paul Gimson, Improvement Cymru, Public Health Wales
- Dr Sam Page, Head of Primary Care, Swansea Bay UHB

Methodology

The Task and Finish Group met on five occasions in August 2020 and discussed literature and personal experiences in Clinical Governance, Quality & Safety, and papers submitted and presented by members. There was specific consideration of existing policies and protocols from Health Boards, publications from the RCGP, and the NHS in Scotland and England, as well from the World Health Organisation. MS Teams was used to facilitate meetings and provide a library for literature collated by a non-systematic literature search and personal contributions. Individual and group interviews were conducted with stakeholders, including GPC Wales executive. The opinions of the Primary Care Reference Group, with its rich mix of nursing, therapies and stakeholders representatives, were also sought. Stakeholders who contributed through individual and group interviews included;

- Jonathan Webb, Welsh Legal and Risk, NWSSP
- Martyn Waygood, Interim Vice Chair & Independent member (legal), SBUHB
- Pamela Wenger, Director of Corporate Governance, SBUHB, Chair of National Board Secretaries Peer Group
- Dr Sion Edwards, Primary Medical Care Advisory Team (PMCAT), NWSSP
- David O'Sullivan. Chief Optometric Advisor
- Dr Colette Bridgman, Chief Dental Officer (written evidence)
- Primary and Community Care Reference Group (workshop discussion on 20th August 2020)
- GPC Wales Executive (workshop discussion on 19th August 2020)
- Dr Andrew Carson-Stevens, Clinical Reader of Patient Safety and Quality Improvement, Patient Safety Research Group (the 'PISA group') in the Division of Population Medicine, School of Medicine, Cardiff University
- Dr Andrew Havers, SMO Primary Care, Welsh Government (written evidence)

The Task and Finish group also had access to published evidence from the Health Foundation, Nuffield Trust, HIW and Public Service Ombudsman and the Older Persons' Commissioner for Wales.

2. Case for Change

NHS Core Values

In Wales there are five core values in the NHS. The first listed is:

Putting quality and safety above all else –
providing high value evidence based care for our patients at all times.

A Healthier Wales (2018) then continues to propose organisational values which include

Measuring the health and wellbeing outcomes which matter to people, and using that information to support improvement and better collaborative decision making. Proactively supporting people throughout the whole of their lives, and through the whole of Wales, making an extra effort to reach those most in need to help reduce the health and wellbeing inequalities that exist

The Quadruple Aim

A Healthier Wales (2018) also describes how the use of the interlocking quadruple aims in the NHS Wales system “will help us learn and share with other health and social care systems, so that we can share experiences and speed up learning”.

The four themes of the Quadruple Aim,

- **Improved population health** and wellbeing
- **Better quality** and more accessible health and social care services
- **Higher value** health and social care
- A **motivated and sustainable** health and social care **workforce**.

By focussing on better quality and higher value in a consistent way in all HBs, variation, waste and harm can be reduced consistently across the NHS system in Wales. However, improved population health and well-being and a motivated workforce are dependent on higher quality and value of services.

Definition of Clinical Governance

A system of Clinical governance is defined in the National GMS Contract for Wales (2004) as:

“a framework through which the Contractor endeavours continuously to improve the quality of its services and safeguard high standards of care by creating an environment in which clinical excellence can flourish”.

All GMS contractors must demonstrate effective governance arrangements (Part 19, 474, GMS Contract Wales) and assurance must be part of this arrangement to enable any Health Board to be confident that the desired level of quality is being delivered by GMS contractors while remaining sustainable, efficient and effective.

Whilst most health care professionals practise to a very high standard, it is essential that all Health Boards also have in place a robust assurance framework to identify and share best practice, recognise where additional support may be needed and to highlight when things are going wrong at an early stage in general medical service provision. Patients must be able to rely on consistently high quality care and experience and by developing transparent, rigorous and timely review and assurance processes, GMS contractors will be provided with the data and feedback they require to engage with continuous improvement.

Community Optometrists, Dentists and Community Pharmacists must also operate under a system of governance that reflects the common standards of all healthcare in Wales as well as the individual requirements of their specialty.

Any Clinical Governance framework should recognise that early engagement between the Health Board and Contractor presents the best opportunity to support practices in making effective and sustainable changes to support service improvement should this be found to be appropriate and necessary.

What is Quality in Primary Care?

There is no one definition of quality in general practice. However, the Health Foundation (No.23 *Improving quality in General Practice, 2014*) concluded that “An appropriate conceptualisation of quality depends on what the information will be used for. Contextual factors such as location, policy priorities, discipline, demographics and measurement approaches all influence what is valued as good quality”.

Where frameworks of quality in health care exist, there is a focus on patient experience, clinical effectiveness and safety. Considering general medical practice in particular, there is a need to consider including holistic care and generalism as well. Dental Contractors are being encouraged to focus on outcomes for patients rather than counting treatment processes. Optometrists in the United Kingdom have developed online systems for self-assessing governance.

What is Safety in Primary Care?

Every day thousands of people in Wales visit their GP, practice nurse, pharmacist, optometrist or dentist, or receive service from directly employed staff. Most receive safe, high quality care but it is estimated that in 1-2% of consultations there may be an error, whether or not it is evident to patients (*Evidence Scan: Improving Safety in Primary Care*, Health Foundation (November 2011). Some errors may lead to catastrophic consequences for patients and the practitioners, such as emergency admissions, permanent disability or even death.

What is the frequency of Patient Safety Incidents in Wales?

From research conducted in primary care by a collaboration of academic safety researchers, including Cardiff University, ‘*Explore the nature, range and severity of general practice-related incidents as reported to the NRLS from Primary care in England and Wales*’ (NIHR) it is possible to estimate the incidence of harm. For example, using the definition of ‘severe harm’ from a Patient Safety Incident as being

“where the patient was harmed causing a long term or permanent impact on physical, social or mental function or shortening of life expectancy”

- **Errors** of any type occur in 1% to 29% of GMS Consultations
- A Prescribing error occurs in 11% of consultations
- **Harm** of any type occurs in 2%-3% in-hours consultations, and 2% of OOH consultations
- Of these 1 in 25 Harms are **Severe Harm** (as defined above)

[Panesar SS, deSilva D, Carson-Stevens a, Cresswell KM, Salvilla SA, slight SP, et al. How safe is primary care? A systematic review. BMJ Qual Saf. 2016;25:544–53]

When presented with these figures, many professionals may question their face validity as they do not feel they match their lived experience at the frontline.

There is currently no publication of patient safety incidents in primary care or requirement for GMS practices to report such severe incidents. There is also no requirement for sharing the learning with neighbouring practices or clusters, or with practitioners in other parts of Wales.

HBs are thus unsighted on the harm or risk of harm that is currently experienced in GMS practices.

How do LHBs measure clinical governance, quality or safety?

In *Health and Care Standards* (WG/NHS Wales, 2015), the listed standards are described as forming the cornerstone of the overall quality assurance system within the NHS in Wales. They are grouped according to the headings in the figure below.



However, there is no single nationally agreed interpretation of the standards that sit below these headings as they apply to primary care and community services in Wales. Attempts have been made within the last decade:

1. to define 'primary care measures' (two iterations) using a modified Delphi process
2. to publish such measures on the Primary Care Information Portal
3. to create a clinical governance practice self-assessment toolkit and incorporate this in the QOF/QAIF sections of the GMS contract.

However, these have fallen short of creating a robust governance framework because

- data was not available or inconsistently interpreted
- updating of data is slow (often published 2-3 years after the clinical event)
- participation was voluntary, and HBs struggled to enforce improvements

In general, HBs may thus be unsighted on the level of quality and risk of harm that is currently experienced in GMS practices (and in other independent contractors).

COVID-19

The Coronavirus pandemic has highlighted the need for clarity as to the essential services to be delivered consistently by the NHS in Wales, even during a COVID-19 outbreak. The Directors of Primary Care have pushed ahead with developing a definition and set of metrics for essential services, based on the World Health Organisation classification, with the addition of COVID-19 services. These are being produced by the Strategic Programme for Primary Care in Wales. The relationship between these metrics and any metrics for Quality and Safety needs to be explored and defined.

Use of Data

Solberg et. Al. in *'The Three Faces of Performance Measurement: Improvement, Accountability and Research'* 1997, described how data can be used in health care for quality improvement, quality assurance/judgement, or research. The characteristics of the data for each of these purposes are different (e.g. continuously supplied versus once-off extraction; small sample versus comprehensive collection). Consequently, appropriate structures and processes need to be in place in each LHB and/or nationally if governance, quality and safety are to be assessed effectively.

Learning from GMS and GOS Performers list cases

One specific aspect of governance that HBs are responsible for is the management of medical and optometry professionals on the HB performers lists. Although there is a recently revised standard operating procedure for medical performers that has been accepted in most HBs, there is no agreed mechanism for ensuring the consistency of standards used and triggers for taking action across all 7 HBs. There is no formal mechanism for sharing learning from professional concerns management. The role and use of Primary Care Medical Advisory team (PMCAT) is not agreed.

Other Independent Contractors

The principles described here also apply to other services and professions: community optometry, community pharmacy and general dentistry. However, we should recognise that community pharmacists do not have performers lists, and that intricate governance monitoring processes already exist for community dentistry (e.g. Health Inspectorate Wales, and HBs' formal contract monitoring processes). Furthermore, dental performers list procedures in Wales also contain a national group for sharing learning and discussing performance cases. There is much that can be learned from these existing processes that could be applied elsewhere.

Good practice

Some HBs have established sophisticated local governance frameworks which are used and refined to monitor performance against contracts held by GMS contractors. In one HB, there is a rigorous approach to practice visiting by managers and clinical leaders using a balance between risk-based and random sampling. In another, there is risk-based Governance Framework with objective data being reviewed annually to determine which practices are selected for further review. The depth of reviews are also determined by the level of risk. Independent members of the health board also participate and seek patient experience views. In a third there is a framework based on the Clinical Governance practice self-assessment toolkit. A fourth is yet to systematise visiting programme.

Co-Production

The voice of the patient and the carer needs to be reflected in the design and operation of primary care services. As yet this is poorly developed in governance processes but is becoming increasingly seen as some Health Boards now seek opinions of independent members on appraisal, revalidation procedures and practice GMS practice governance visits. It is useful to consider the following definition of co-production from NEF (the New Economics Foundation) and NESTA (National Endowment for Science, Technology and the Arts):

'delivering public services in an equal and reciprocal relationship between professionals, people using services, their families and their neighbours'

In the 1000lives campaign Tools for Improvement series no 8, 'Co-producing services - Co-creating health' (2013), authors suggested that:

"Co-production requires a shift in power from service providers to citizens. This results in a need to re-think what we mean by professionalism and leadership in health and social care, and a re-examination of risk management and professional boundaries... Co-production encourages participation, mutuality and respect for others, valuing the experience, skills and knowledge that each participant brings and providing opportunities to extend their skills and knowledge. It aims to change 'traditional relationships of power, control and expertise' and the relationship between state and citizen."

Consequently, it is only right that we consider how patients' experiences and outcomes, and thus quality and safety in primary care, can be enhanced through co-production.

3. Assessment

The Task & Finish (T&F) group considered the evidence and agreed the following four key areas for further development led by the Strategic Programme for Primary Care.

1. Creating an Overarching Clinical Governance Strategy for Primary Care
2. Building a National Framework for Assurance
3. Supporting Clinicians to Learn and Improve
4. Developing the Tools to Enable Safe, Sustainable, Quality Care

The rest of this section describes the views shared in the T&F group and the recommendations made, together with specific actions to be undertaken.

3.1 Creating an Overarching Clinical Governance Strategy for Primary Care

The Task and Finish group (T&F) considered the evidence and submission from HBs, the experience of clinicians and patients, stakeholders and published academic literature. It noted the great variation in how Clinical Governance was viewed and also how systems of assurance varied between countries, between the devolved nations in the UK and also within Wales. It was noted that there was often confusion or imprecision in the use of the terms of quality assurance, improvement, planning and control. Examples of good practice in governance were found, including from within Wales.

There was no desire to maintain the status quo, but there was recognition that many agencies were involved in aspects of governance and each viewed the problem through a different lens. It was considered important that a consistent approach was adopted across Wales that open and transparent yet effective and efficiently delivered. Acceptability to professionals and patients was crucial, both in terms of validity but also of workload, as well as being resourced realistically.

Contractual changes may be necessary to ensure contractors and professional behaviours align with the Model. There must also be clear expectations from Welsh Government and Health Board executives responsible for Clinical Governance that the Model is seen as the means of deriving assurance, improvement and planning in primary care.

Recommendation

1. There should be **a single *Welsh Model of Clinical Governance in Primary Care* and it should be adopted and implemented by all Health Boards**. It will cover all aspects of quality & safety relating to independent contractors, directly managed services and clusters. This system model should describe **principles, standards & best practice**. It should be designed nationally but implemented locally by all HBs as part of their whole pathway approach to clinical governance. It will reflect the importance of the contribution of services in primary care and the community to quality and safety of the whole health system. Through implementation of the model, Welsh Government should expect consistency in clinical governance across Wales.

This system should be closely aligned to forthcoming policy from the Welsh Government in the form of the Quality and Safety Plan and also forthcoming guidance from the World Health Organisation. It should therefore be considered as interim model to be reviewed at a later date. It should inform and align to HB organisational Quality Plans. Where possible, the model should be based on existing good practice in primary care and be endorsed by professional bodies, such as the RCGP, GPC-Wales and equivalents for other independent contractors.

The ***Welsh Principle of Clinical Governance in Primary Care* should comprehensively describe and define the system components** as they apply to primary care, and describe how they work together and how they are to be implemented;

- Quality Assurance
- Quality Improvement

- Quality Planning
- Quality Control
- Quality Management
- Organisational Duty of Quality
- Organisational Duty of Candour
- Organisational Culture
- Incident Reporting
- General Practice Medical Indemnity(GPMI)
- Peer review and Self-assessment
- Assessment of Maturity
- Organisational Learning from incidents
- Accountability
- Board awareness of Primary Care & Community Clinical Governance
- 'Just Culture', balancing openness, learning and performance measures
- Co-production of quality and safety with patients and carers
- Patient Reported Outcome Measures and Experience Measures
- Value-Based Health Care
- Research into quality and safety in primary care

Reforms to Independent Contractor contracts may be necessary to systematize the *Welsh Model of Clinical Governance in Primary Care* e.g. consideration of regular protected time for clinical governance activities, reporting of significant event analyses, increased reporting of patient safety incidents etc.

3.2 Building a National Framework for Assurance

The Task & Finish group noted that each HB had its own way of seeking assurance from GMS contractors, with a wide variation in sophistication and coverage. Some used objective criteria to trigger a visit whereas some used random selection. HBs used patient experience to differing degrees in judgements in assurance processes. e.g. direct face to face questioning on site, or analysis of complaints or ombudsman reports. The role of patients in helping to design frameworks was discussed, as were the resources required for operationalising frameworks.

Metrics were considered and there was acknowledgement that it was possible, for example, to map an indicator to Health Care standard to use a measure for assessing whether a service was being operated safely, but as long as environmental factors and population demographics were taken into account. It was acknowledged that such data might identify outliers, and this would trigger further local enquiry. Experience has shown that when this had happened in the past, a supportive approach rather than a punitive one produced the best results. An example of a Governance assurance framework for GMS currently in use, with its suggested metrics, is in appendix A.

Some professionals complained that collecting and submitting data to HBs was onerous and disproportionate to the benefit. Some HBs use local data analysts and readily available data extensively yet others either do not have access to this resource, or choose not to use it. Some questioned the continued role of the Clinical Governance Practice Self-Assessment toolkit and its usefulness, especially if triggers were not followed up.

In some HBs, dental contractors were supported with pre-HIW inspection visits by primary care teams, but not in others. The higher risks due to radiation and toxic chemicals in dentistry require a different level of scrutiny from other contractors. There was recognition that, whilst allowing for obvious clinical differences in risks, a consistent approach to all contractors would be helpful.

One key message from professionals was that the existing contracts already contain ways to deal with poor performance and that there should be focus on using these contractual levers where necessary. A national framework for assurance would facilitate this by ensuring a consistent approach to highlighting trends and outlying cases, so that further investigation may be performed.

The importance of creating a patient safety culture in organisations which is supportive of clinicians and managers who have concerns and report incidents was noted and has an impact on the motivation and sustainability of workforce, as well as quality and value (cf. *Quadruple Aim*).

There was broad agreement that the role of patients and carers in supporting clinical governance measures needed definition and strengthening. An agreed approach to co-production could help systematize the voices of patients and carers in the operation of governance processes. Welsh examples exist where independent members participate in practice visits or where patient or citizen panels are polled for their views on local primary care services.

Recommendations

2. Building on current good practice and working within the *Welsh Model of Clinical Governance in Primary Care*, a **single national framework for Quality Assurance of Independent Contractors** should be agreed. The framework should be based on the Healthcare Standards for Wales and, where possible, should be populated by existing data to minimize demands on contractors to provide new data. The framework will have multiple dimensions and will include data from a wide variety of sources, e.g. from clinical activity, NHS administration, external reports and patient experience. For clarity, this framework is primarily for use by Health Boards for assurance rather than for independent contractors to use as the “*system of clinical governance*” required of them in the general medical services contract.
3. The **patients’ and carers’ voices will be an integral part of governance systems** in primary care, including a single national framework.

3.3 Supporting Clinicians to Learn and Improve

A key message from professionals and the RCGP was that any governance system should primarily be seen as supportive and where possible, formative in feedback. This is in contrast to cultures and processes that are sometimes perceived as punitive and creating a climate of fear that prevents sharing of learning. Good practice was noted in some areas of Wales where GPs met regularly with other practices to discuss Clinical Governance issues, supported by the HB.

The need to ensure that effective learning occurred from patient safety incidents and also good practice examples was emphasised. It was recognised that lessons learned from incidents needed to be shared widely and where possible nationally, using effective feedback or ‘learning loops’. This would inevitably mean that lessons would have to cross traditional organisational boundaries.

The advent of the medical examiner system in Wales from 1st April 2021 present a challenge in how HBs and GMS practices will manage the requirement for mortality reviews without a coordinated supported from medical leadership within HBs.

The separate independent contractual performance systems in Wales were discussed, and the different approaches to managing performance concerns and sharing learning from cases were noted. There was recognition that closer alignment between the professional groups would be beneficial with respect to sharing learning. The complete lack of a standard operating procedure for optometrists was seen as a significant weakness.

The role of PMCAT and potential evolutionary changes were discussed. No firm conclusion was possible in this rapid review, but further work was agreed to be necessary.

There was a concern that much discussion was centred on top-down approaches that might be viewed as ‘impositions’ on frontline clinicians. There was support for more ‘bottom-up’ opportunities to share learning with peers, especially where innovations had been tried and tested. This could include the multi-professional and multi-agency settings of clusters and primary care teams for self-assessment and peer-review.

Recommendations

4. The **use of peer review and self-assessment in clinical governance in and between practices, services and clusters** will be developed and implemented, and any innovations and learning will be identified and shared '*from the bottom up*'. The peer reviews and self-assessments will reflect the multi-professional and multi-agency make-up of clusters and primary care teams.
5. **Learning from individual incidents** and from themes identified from aggregated incident reports **should be shared routinely** using established effective and robust mechanisms for learning. **Learning from mortality reviews** conducted following the introduction of the new medical examiner system for Wales should also be included.
6. **A national approach to sharing learning from professional performance cases** of independent contractors will improve standards of case handling and may help prevent or avoid escalations. The ongoing role of the Primary Medical Care Advisory Team (PMCAT) in these performance processes needs to be considered. A standard operating procedure for managing concerns regarding the general Optometrist performers list is needed.

Developing the Tools to Enable Safe, Sustainable, Quality Care

The historical low levels of incident reporting in primary care were considered and the current "*not fit for purpose*" system of Datix discussed. It was recognised that with the impending launch of the 'Once for Wales Concerns Management System', there is a new opportunity to change the culture of reporting in primary care for the better and support primary care practitioners in their delivery of care. Mindful of the context of the legislative changes enshrining the incoming duty of organisational quality and duty of organisational candour, improved incident reporting and learning was perceived as essential. It was agreed that feedback to the reporter after reporting incidents was key in the new system.

Multiple sources of data that tell us much about quality and safety in primary care in Wales were recognised to already exist. These include some data from incidents in primary care, data from clinical and administrative parameters, financial data and outcome and experience measures from patients. Currently much is available locally but is variably used or analysed to deliver a significant change. The T&F group saw the potential in the 'Big Data': data from 404 general medical practices, 64 clusters and their population demographics, over 1500 general dental practitioners, and hundreds of community pharmacists and optometrists, not forgetting district and other community nurses and therapists. The T&F group believed that a nationally coordinated analysis by experts used to working with such 'Big Data' would multiply the impact of the data. e.g. Through greater numbers and use of 'live' data, statistical analyses can be more detailed and trends (whether positive or negative) can be spotted earlier and action taken. Quality improvement at scale and at pace could be possible. Assurance analyses would mean that genuine outliers could be supported and local environments and population demographics taken into account. The data should be securely published and available according to standard information governance principles, with any data extracted and analysed for a defined purpose, and analysed and shared on a need-to-know basis.

Such data will be of enormous value to improving the quality of services and planning. It will also be very useful to academic researchers in the field of quality and patient safety. Wales is already lucky to have an international research centre in patient safety in primary care, in Cardiff University. However, the NHS in Wales and academic researchers are not closely working together to ensure the whole population of Wales benefits from this world-class academic resource. The T&F group also noted the Clinical Effectiveness Group at Queen Mary, University of London and Tower Hamlets CCG which have developed a synergistic relationship and supported GP clusters to improve mortality and morbidity in long term conditions management.

Recommendations

7. The '**Once for Wales Concerns Management System**' will be used for all incident reporting in Wales by all NHS organisations, including independent contractors.

8. **Data from a wide variety of primary care services, including independent contractors, should be analysed at national level** to ensure validity and reliability of analyses through 'big data', and then selectively published to different audiences.
9. **A close and dynamic link should be established between the Strategic Programme for Primary Care and academic researchers into quality and safety in primary care.** This will ensure that primary care clinicians, patients and the Welsh population as a whole benefit from the latest evidence-based findings in quality improvement, clinical effectiveness, implementation science, and patient safety research

Conclusions

The T&F group identified the following nine recommendations:

1. Clinical Governance in Primary Care in Wales is complex and variably delivered by HBs and providers. All 7 HBs need to adopt and implement a single strategic model that pulls all the strands together and organizes the complexity.
2. A single multi-dimensional framework for quality assurance, based on the above model and Health care standards for Wales, needs to be adopted and implemented by all 7 HBs for independent contractors.
3. Some independent contract reform may be required to maximize effectiveness of clinical governance processes, but it is more important to use existing contractual levers when necessary
4. Systems, Processes and Pathways must be developed to support primary care clinicians to learn from others across Wales
5. Data needs to be shared and analysed by specialists at national level, and securely published at the appropriate level as part of everyday NHS processes, to reap the benefits of 'Big Data' in primary care.
6. Existing data should be mined first where possible and should be from multiple sources.
7. Patients and carers should co-produce clinical governance
8. Links between the primary care and research into Quality & Safety needed to be strengthened
9. The Primary Care Medical Advisory Team's future needs further deliberation in the view of the proposed development of the model and assurance framework

These recommendations have been grouped into four areas as follows where action is required:

- Creating an Overarching Clinical Governance Strategy for Primary Care in Wales
- Building a National Framework for Assurance
- Supporting Clinicians to Learn and Improve
- Developing the Tools to Enable Safe, Sustainable, Quality Care

Appendix A

General Medical Services Governance Assurance Framework Measures		
Domains	Triggers	Comments
Staying Healthy	<ul style="list-style-type: none"> Childhood & Flu Vaccination Rates (<2SD) 	<ul style="list-style-type: none"> Indicate robustness of practice systems
Safe Care	<ol style="list-style-type: none"> Coroner's Court adverse findings Upheld Ombudsman complaints Serious incidents on DATIX directly related to practice system/Staff (if not reported by practice) Enhanced Service Audits CGPSAT – not completed or domains scoring 2 or less Information Governance Audit not completed or new Concerns POVA/Safeguarding (Datix Incidents) Drug and Safety Alerts Practice & Practitioner Performance Issues –Medical performance Lists & Performance Advisory Group. HIW Inspection Reports – critical outcomes 	<ol style="list-style-type: none"> Adverse court findings may suggest poor safety in practice Upheld Ombudsman complaints may suggest poor safety or management systems. SI may suggest poor practice safety system Lack of Audit or Poor audit outcomes may reflect poor practice Lack of CGPSAT or Persistent low scores suggest failure to progress in Q&S Lack of Information Governance Audit or Poor audit outcomes may reflect poor practice Cases may suggest poor safety in practice Lack of action may suggest poor safety culture Conditions from reference panel and GMC suggest impaired practice safety mechanisms Adverse HIW recommendations may suggest poor systems for clinical governance
Effective Care	<ul style="list-style-type: none"> QoF Diabetes Scores <2SD in Wales QoF COPD Scores <2SD in Wales Adverse PPV Reports – significant reclaims 	<ul style="list-style-type: none"> Low scores may suggest that chronic conditions is poorly run Adverse PPV reports suggest poor systems for clinical governance and probity
Patient Experience	<ul style="list-style-type: none"> Compliments Complaints 	<ul style="list-style-type: none"> Themes shared at QSI and Learning and Assurance Developing response writing training Scoping exercise underway with HB Lead for appropriate PROM for our Unit Staff trained in taking patient stories and staff stories
Dignified Care	Care Homes <ul style="list-style-type: none"> Unscheduled admission rates >2SD Deaths in hospital within 2 days >2SD Pressure ulcers >2SD 	<ul style="list-style-type: none"> Data may suggest poor engagement with care home staff or care home DES

General Medical Services Governance Assurance Framework Measures		
Domains	Triggers	Comments
Timely Care	<ol style="list-style-type: none"> Composite of GP OOH and ED minors attendances >2SD Significant complaints about access, CHC Access visits Patient Registrations – internal transfers LHB/CHC/LMC agreed Access Standards 	<ol style="list-style-type: none"> Shows primary care workload delivered outside of in-hours service Patient feedback may indicate poor performance Internal patient movement may indicate poor performance Failure to meet agreed core standards indicates poor access
Individual Care	<ul style="list-style-type: none"> Prescribing Safely >2SDs ; monitoring a range of agree parameters, including the national prescribing indicators 	<ul style="list-style-type: none"> Practice patterns can be indicators of high workload, poor safety and prudent prescribing cultures.
Staff & Resources	<ul style="list-style-type: none"> Sustainability Scores >55 	<ul style="list-style-type: none"> At risk in next 12 months and thus safety systems potentially under strain.

Key

<2SD means less than two standard deviations from the mean

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