Framework for
Public & Service
User Involvement
in
Health and Social Care
Regulation in Ireland

HEALTH & SOCIAL CARE
REGULATORY FORUM

December 2009

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1 Introduction

1.1 THE HEALTH & SOCIAL CARE REGULATORY FORUM

There are a number of regulatory bodies in the health and social care sector in Ireland with responsibility for regulation of areas such as professional practice, service quality and medicines and healthcare products (See section 2.2 for more detail). The Health and Social Care Regulatory Forum was established in 2008 to provide a mechanism for exploring opportunities to harmonise certain business processes, share best practice and facilitate coordination where appropriate between member organisations. It also aims to share knowledge and expertise on matters of common interest with a view to enhancing the overall practice of health and personal social services regulation in Ireland for the benefit of public health. One such advancement of the forum in this regard, has been the development of a joint framework for public and service user involvement in health and social care regulation in Ireland.

Box 1.0

What is Regulation? Regulation occurs when an external agency imposes standards or rules on the behaviour and actions of others which are accompanied by enforcement provisions. It is often associated with the licensing or accreditation of professionals and organisations and is typically based on three activities:

- **Direction:** communication of expectations and requirements
- **Surveillance:** assessment of performance and compliance with standards, targets and rules
- **Enforcement:** use of positive or negative powers to bring about change.[1]

Regulation is designed to safeguard the interests of service users and the public, assist the subjects of regulation to enhance their performance and create public confidence in the services provided by them. The Irish government defines a regulatory body as a body that has statutory recognition and has functions in at least two of the three above activities.[2]

1.2 IMPETUS TO PUBLIC/SERVICE USER INVOLVEMENT IN REGULATION

"An open culture… between Government and citizen is essential if confidence is to be maintained in the institutions of State"[3]

Historically, the point of contact for citizens with government has occurred only when citizens go to access public services.[4] However, it is increasingly being recognised that a successful society depends on partnership - between citizens, civil society and the public service with respectful dialogue allowing the government, citizens and communities to seek the common good.[5] The OECD[6] recommended that the Irish Public Service place greater focus on citizens and their expectations, and on targetting delivery of services from their perspective to achieve broader societal goals. Doing so will allow the State to remain relevant in the eyes of the citizen and will offer an unprecedented opportunity to enhance Ireland's democracy.

An important initiative in terms of having citizen-focussed public services was the launch of the Quality Customer Service Initiative (QCS) in 1997. The QCS initiative set out 9 principles of customer service (now 12) to which all public servants should adhere. These included the provision of clear, timely and accurate information; maintaining a well publicised accessible, simple and easy to use complaints system; and providing a structured approach to meaningful consultation. In 2002, the Customer Charter initiative was then announced providing customers with a clear and unambiguous statement of the level of service they could expect to receive from a Government Department or Office.

Service user and public involvement in the area of regulation of health and social care is a relatively new departure in the state. Traditionally, consultation has been one of the primary mechanisms by which the public and service users have been involved in public service delivery and public policy. The Government committed in its white paper on *Regulating Better*[7], to consulting more widely with stakeholders before regulating in line with the principle of transparency. In 2006, guidelines on consultation for public bodies were published with the aim of promoting better quality public consultation.

The importance of involving service users and members of the public in health and social care services has been a recurring theme in a number of recent Irish policy documents[8] and was given most prominence with the publication of the *National Strategy for Service User Involvement in the Health Service 2008-2013*.[9] This strategy identifies three levels at which service users can be involved in the health services i.e. as individuals involved in their own care, at a community level involved in local service delivery and development and at a national level whereby strategic policy is informed through the involvement of service user organisations in partnership with health care professionals.[10] It is this latter level which is of most relevance to the work of regulatory bodies in Ireland.

Most recently, the report on the Commission for Patient Safety and Quality Assurance included a number of recommendations aimed at strengthening the regulatory framework in health and social care in the state and in particular, the recommendation that robust and validated patient and public involvement should be a requirement for all healthcare oversight, scrutiny, quality control and other accountability mechanisms.[11] This reflects a recognition that the primary duty of regulatory bodies is to their customers and members of the public.

There is now a general acceptance that citizens and service users should be considered as partners playing a formative role in the work of regulatory bodies. The Task Force on the Public Service set up in response to the OECD report on the Irish public service, called for future citizen engagement in policy and service delivery issues beyond conventional communication, public consultation and citizen participation mechanisms employed heretofore. *"It [the public service] must deepen its dialogue with the citizen".*[12] According to the Taskforce on Active Citizenship [13], one of the foundations of active and engaged citizens is enabling and empowering decision-making as close to the citizen as possible. The government is committed to a social partnership approach across the policy spectrum and the life cycle approach which is adopted in *"Towards 2016 Ten Year Framework Social Partnership Agreement 2006-2015"*, places the individual firmly at the centre of policy development and delivery.

Box 1.1

The term *"service user"* is used throughout this document. Service user is preferred as it is the term used in the National Strategy for Service User Involvement in the Health Service. For the purposes of this document, the term refers to a person who uses or has used health and social care services. Other terms such as customer, consumer, client, patient or licensee may also be relevant depending on the role and functions of a particular regulatory body. The term *"public"* is used to refer to people who are potential users of health care and social care services. This term is interchanged at times with the term *"citizen"*, which is also frequently used in the literature. Service users and the public can include:

- Those who use or have used health and social care services;
- Representative bodies;
- Parents, carers and guardians; and
- The wider public i.e. people who are potential users of health care and social care services.

Service users will normally comprise the former two categories and the public will consist of the latter group. Parents, carers, and guardians, where applicable, can fall into any of these groups. It is important to distinguish between service users and the public as they will generally have different aims and objectives when involved in the regulation of health and social care. For instance, we could reasonably expect a current service user to care more about the quality of treatment and services for people with his or her health condition in the care setting that he or she has experience of. Public concerns are likely to be much broader in scope.

The recent report of the Commission on Patient Safety and Quality Assurance makes 25 recommendations for involving "patients, carers and service users as partners" in healthcare. These fall under 3 headings: *"Patient, carer and service-user participation"*, *"Knowledgable patients"*, and *"Open communication with patients following an adverse event"*. Considered of particular relevance to the work of the regulatory forum are the following recommendations, which fall primarily under the first heading:

R4.1 *The proposals in the National Strategy for Service User Involvement in the Irish Health Service should be implemented as a matter of urgency to ensure that patients and their families can influence policy development, service delivery and health service development and evaluation.* [i]

R4.2 *A national network of patient advocates who will work in partnership with healthcare organisations and other key players to improve patient safety should be identified, supported and developed through appropriate training programmes; the network should also, where appropriate, have strong links with international/worldwide initiatives.*

R4.3 *Effective patient and public involvement should be demonstrated in any review of health service performance.*

R4.4 *Robust and validated patient and public involvement should be a requirement for all healthcare oversight, scrutiny, quality control and other accountability mechanisms.*

R4.7 *Opportunities must be provided for service-users to contribute to the education of future healthcare professionals and to the continuing professional development of existing practitioners.*

[i] *The proposals contained in the strategy include: commitment at all levels of an organisation to service user involvement; adopting a systematic approach to effective involvement, patient charters, specific work to ensure the involvement of young people and excluded groups; developing existing structures; and learning and development programmes to meet these goals.*

R4.10   Patient engagement should be advanced as a recognised patient safety solution. Amongst other things, this will enable a better understanding of what patients and families want in relation to disclosure and learning from adverse events and the development of an appropriate communications process to deal with such events.

R4.11   In relation to complaints handling, patients and carers should have a clear understanding of the procedures and processes involved. Patient involvement in the design of standards and implementation processes is crucial to transparency and effectiveness.

R4.14   All public information should be easily accessible, available in a variety of formats and media and culturally and socially appropriate; it should enable use of advocacy and interpretation services as appropriate. The information should be quality assured and readily identifiable as being from an authoritative and standardised source.

R4.15   All health policies and plans developed by the Department of Health and Children, the HSE and HIQA should be required to contain a statement on how patients, carers and service-users were involved in the development of the policy.

R4.16   National standards for open disclosure of adverse events to patients should be developed and implemented.

1.3   BACKGROUND TO GREATER PUBLIC/SERVICE USER INVOLVEMENT

The encouragement of greater service user and public involvement in the health services arose for a number of reasons. Of particular importance has been a number of international studies on adverse events in the health services. For example, an EU study carried out by the European Commission on the impact of Information Technology on patient safety highlighted that approximately 10% of patients admitted to a hospital are unintentionally harmed.[14] Similar studies have mirrored this finding and raised public concerns over the quality and safety of health and social care services leading people to question the assumption that the doctor or health professional always knows best. Public concern has also been augmented by high profile cases such as the Inquiry into the level of caesarean hysterectomies at Our Lady of Lourdes Hospital in Drogheda, and the findings of the Shipman Inquiry in the United Kingdom. These events have all affected public trust in health professionals and health services.

Service users have also been demanding a more equal relationship with their health professionals and are no longer accepting the traditional role of the patient as a passive recipient of care. Their calls for greater involvement in their own care have been heard and have also encouraged government and health providers to formulate policies with more ambitious objectives of encouraging the involvement of service users in the planning and delivery of health and social care services.

1.4   WHY PUBLIC/SERVICE USER INVOLVEMENT IN REGULATION IS IMPORTANT

Increased levels of public and service user involvement should lead to greater openness and transparency among Irish public bodies. According to the group who produced the *"Delivering Better Government"* report, adopting a partnership approach will promote greater openness and build deeper relationships in the interest of delivering a better public service.[15]

With the traditional model of self-regulation having come under scrutiny in the health field [16], there has followed a growth in the number of regulatory bodies and regulatory strategies. The Democracy Commission reported that the growth in the number of public bodies (regulatory and non regulatory) in recent years has lead to modern government becoming, in some ways, *"opaque and impenetrable"* to citizens and advocacy and civil society groups. The Commission also highlighted the increasing involvement of the private sector in the provision of essential services such as hospital and nursing home care in the absence of adequate systems of regulation and protection.[17] Therefore, the need to involve service users and the public has become increasingly important in recent times.

Service users and members of the public should be involved in the work of regulatory bodies:

- To promote **openness and transparency** by enabling the public to review service quality and be directly involved in the development of rules and standards;
- As a **safety solution** so that health and social services can learn from the experiences of service users, carers and others, particularly as it relates to adverse events;
- To **improve the quality** of regulated services by ensuring that services are sensitive to the needs and preferences of service users and the public; and
- To focus the work of regulatory bodies on service users and **encourage public accountability** by complementing the expertise of health professionals and information from scientific literature[18].

A further rationale for involving the public directly in the work of regulatory bodies is a need to counteract the risk of **regulatory capture**.

This can occur when the regulator becomes too close to the professionals or organisations being regulated, as described by Ashworth, Boyne and Walker:

"In these circumstances, the capacity for independent judgement is undermined or lost, and information on performance is likely to be biased. Such capture may be especially likely to occur when the staff on the two sides of the regulatory relationship are drawn from the same professional group, when 'poachers turn gamekeepers' (or vice versa), and if there is a long-term relationship between individuals in the regulatory and regulated organisations".[19]

As evident above, there are numerous reasons why involving the public and service users in the work of regulatory bodies is important, but the salient reason for doing so is so that Ireland can provide a world class public service. Wherever public services are considered excellent around the world, three characteristics are typically present, **new professionalism, strategic leadership and citizen empowerment**.[20]

This document proposes a framework for involving service users and the public in the work of health and social care regulatory bodies in Ireland through examining current practice in Ireland and good practice in other states. Chapter 2 focuses on methods that regulatory bodies in the health and social care arena in Ireland are currently using to involve the public and service users in their work as well as other initiatives in the health and social care services. Chapter 3 identifies good practice internationally in the area and takes a look at how Ireland is fairing in an international context. Finally, Chapter 4 provides a framework for public and service user involvement in health and social care regulation in Ireland including possible areas of future collaborative working amongst forum member organisations.

2   The Irish Context

2.1   INTRODUCTION

This chapter examines how members of the public and service users are currently involved in health and social care in Ireland. It initially sketches the health and social care regulatory landscape in Ireland. There follows a brief overview of public and service user involvement in health and social care that concentrates on recent initiatives to increase their participation. Finally, the chapter examines the degree to which the public and service users are currently involved in bodies who are members of the Forum of Health and Social Care Regulators.

2.2   OVERVIEW OF HEALTH & SOCIAL CARE REGULATORS IN IRELAND

Most Irish health and social care regulatory agencies have only recently been established. However, regulation in the health and social care area is not a new phenomenon. An Bord Altranais, the regulatory body for the nursing profession, was established in 1950 when it took over the functions of two bodies, the Central Midwives Board and the General Nursing Council, which had been set up in 1918 and 1919 respectively. Table 2.1 lists the agencies who are members of the Forum of Health and Social Care Regulators and indicates the year that each one was established. The table illustrates the significant growth that has taken place since 2000 with 6 of the 13 forum member agencies having been established since then.

It also shows what type of regulation each agency is involved in. For example, the Mental Health Commission and the Health Information and Quality Authority (HIQA) have regulatory powers over health and social care services. There are also professional regulatory bodies such as the Medical Council, An Bord Altranais, the Dental Council and the Pharmaceutical Society of Ireland as well as agencies who regulate health and consumer products, such as the Irish Medicines Board and the Food Safety Authority of Ireland.

2.3   CURRENT PUBLIC AND SERVICE USER INVOLVEMENT IN HEALTH AND SOCIAL CARE

Concerns over the quality of health and social care provision have ensured that there are greater expectations among service users and the public of having more influence over how health and social care services operate and recent policy initiatives illustrate a convergence between national policy and service user and public expectations. For instance, the *National Strategy for Service User Involvement in the Health Service 2008-2013* recognises that *"the service user should be central to their own care and to the design and delivery of health and personal social services".*[21] The strategy identifies three levels at which the service user can be involved in the health services i.e. at the individual, community and national level. Recent initiatives support increased participation at each of these levels. The Irish Society for Quality & Safety in Healthcare along with Health Care Informed launched a "Now We're Talking" practical toolkit for public & patient involvement in healthcare in 2009, which provides healthcare organisations with examples of tools and techniques that can be used for involving the public and patients in healthcare. [22]

Table 2.1: The Regulatory Landscape in Health and Social Care

REGULATOR	YEAR ESTABLISHED
Services	
Health Information & Quality Authority (HIQA)	2007
Mental Health Commission (MHC)	2002
Professionals	
An Bord Altranais	1950 [¥]
Dental Council	1985
Health & Social Care Professionals Council	2005
Medical Council of Ireland	1978
Opticians Board	1956
Pharmaceutical Society of Ireland (PSI)	2007
Pre-Hospital Emergency Care Council (PHECC)	2000
Veterinary Council of Ireland (VCI)	2006 [#]
Products	
Food Safety Authority of Ireland (FSAI)	1999
Irish Medicines Board (IMB)	1996 [*]
Radiological Protection Institute of Ireland (RPII)	1992 [†]

[¥]   *An Bord Altranais was established as a successor to two regulatory agencies in existence since 1918 and 1919 respectively.*
[#]   *VCI was established as a successor to a regulatory agency in existence since 1931.*
[*]   *IMB was established as a successor to a regulatory agency in existence since 1966.*
[†]   *RPII was established as a successor to the Nuclear Energy Board established in 1973.*

The Report of the Commission on Patient Safety highlights the importance of having knowledgeable individuals who are provided with information both on the health system; how it operates, how to access it, how to complain and their rights, and information on a person's condition, options for treatment, how to manage it, and prognosis. The self management movement is gaining increasing attention in recent times. For example, the Irish Society for Quality and Safety in Healthcare this year launched a "Let's Talk: Medication Safety" booklet, a patient educational tool aimed at encouraging the public to play an active role in their medication management and to work in partnership with healthcare providers to reduce errors and improve safe practice.[23] In July 2009, the National Office for Suicide Prevention also published information and advice for the general public on looking after your mental health in tough economic times, which included information on common mental illnesses and details on how to access support services.[24]

The HSE introduced a policy for the national management of complaints in public sector healthcare organisations entitled *"Your Service - Your Say"* in 2008 that aimed to develop a consistent approach to the management of complaints throughout the health services and ensure that complaints lead to quality improvements in the delivery of care.[25] It recognised that providers are fully accountable to the citizens they serve. The HSE and other health providers have attempted to balance the negative image of complaints by expanding their systems to also receive comments or compliments. The HSE's 2008 Annual Report showed that almost 4,900 complaints were received for that year. Seventy-two per cent of complaints were dealt with within the target timeframe of 30 days. The report also indicated that 2% of complainants were not satisfied with the HSE's response to their complaint and requested a further review.[26] However, no indicators have yet been published that provide information on how complaints have led to improvements in the quality of care provided. In terms of mental health services, the Mental Health Act 2001 (Approved Centres) Regulations 2006 places a requirement on all inpatient mental health facilities, including independent providers, to have written operational policies and procedures for the management of complaints and to make individuals aware of the complaints procedure as soon as possible following admission.

Provisions of the Health Act 2007 in relation to the making of "protected disclosures" by healthcare employees, and in certain circumstances members of the public, took effect in March 2009. Disclosures can be made to organisations such as the HSE and regulatory bodies including An Bord Altranais, the Dental Council, the Medical Council, the Pharmaceutical Society of Ireland, the Health and Social Care Professionals Council, HIQA and the Mental Health Commission. Such disclosures should relate to the health or welfare of persons in receipt of health or social care services. They are protected because persons making the disclosures are afforded certain legal protections.

At a national level, Ireland has two general patient advocacy and representative groups whose aim is to influence health policy. Patient Focus and the Irish Patients Association represent the interests of patients with all types of health conditions. In addition to the main patient representative groups, there is a number of organisations that advocate for and represent the interests of people with certain illnesses, impairments or health conditions. For instance, Inclusion Ireland promotes the rights of people with an intellectual disability and the Asthma Society of Ireland advocates for people with asthma.

Government policy supports the increased involvement of such organisations. For instance, the 2006 report of the Expert Group on Mental Health Policy, *A Vision for Change*, recognised that service users should be involved in implementing and evaluating mental health policy and recommended the establishment of a National Service User Executive (NSUE) to achieve this end.[27] The NSUE was set up in 2007 and is now working to achieve the goals outlined for it in *A Vision for Change*. Part of NSUE's work is establishing a national network of service users. Organisations such as Patient Focus and the Irish Patients Association have for example been consulted by the Department of Health and Children and the HSE on policy and legislative initiatives, such as the proposed Health Information Bill and the *National Strategy for Service User Involvement in the Irish Health Service, 2008-2013*.

The HSE also set up a number of Expert Advisory Groups (EAGs) in 2006 in the areas of Older People, Children, Mental Health and Diabetes. Each group contains representatives of service users, carers and members of the public as well as health professionals and they advise the HSE on the organisation and development of services. Each of the EAGs has produced guidelines, protocols and suggestions for best practice in each area. The term of office of each EAG was for 2 years and all of their proposals have been finalised and presented to the HSE Management team. The Chair of the EAG on Older People highlighted the HSE's work on stroke units and diagnostic assessments as evidence of that group's work being taken on board on a practical level by the HSE.[28]

Another representative group that works to influence national policy is the Consumers Association of Ireland. It aims to represent consumers making sure that their needs as consumers of goods and services are given higher priority. As such, its focus extends beyond the area of health and social care to include very different sectors such as finance and telecommunications.

2.4 CURRENT PUBLIC AND SERVICE USER INVOLVEMENT IN HEALTH AND SOCIAL CARE REGULATION

As part of the process in developing this framework for public and service user involvement in health and social care regulation, a questionnaire was developed for circulation to forum member organisations which sought information on the nature of public and service user involvement in their work. Information collected from the 11 respondents to the questionnaire and other sources is presented below.

2.4.1 Methods Used to Facilitate Public and Service User Involvement

All forum member organisations involve service users and/or the public to varying degrees in their work. The most common methods by which they achieve this are through the provision of information and participation in consultation activities which occurs across almost all organisations. Respondents also described methods that are not widespread such as involvement on inspection and review teams. This section examines each of the main methods employed.

A Information Provision

10 respondents to the questionnaire indicated that they provide information to the public usually through newsletters, annual reports and organisation websites. All respondents highlighted their websites in particular as a valuable communication tool. Information included on websites includes the minutes of council and committee meetings in the case of the Pre-Hospital Emergency Care Council. The Pharmaceutical Society of Ireland provides information to patient stakeholder groups and HIQA and the Mental Health Commission make documents available in accessible formats such as in plain English and easy-to-read publications. The Irish Medicines Board highlights new and emerging safety concerns with medicines and medical devices on its website and has a dedicated section on medications, which provides information on medicines that have been authorised for human use.

B Complaints, Concerns and Disciplinary Procedures

Two main types of complaints procedures operate in most forum member organisations. In addition to standard customer complaints procedures, procedures that are related to organisations' regulatory functions are also in place. For example, members of the public can report alleged cases of professional misconduct to An Bord Altranais. Disciplinary procedures in some regulatory bodies also include public representation. The Pre-Hospital Emergency Care Council, the Medical Council and the Dental Council include public representatives on their fitness to practice committees. The Medical Council's Fitness to Practice Committee has a lay majority. The Irish Medicines Board encourages direct reporting of safety and quality concerns by consumers via its website.

C Consultation

Nine of the 11 respondents have involved service users or the public in their work through consultation activities. Most regulatory bodies include a consultation phase in their standards development processes although it also occurs when carrying out review activities and when developing policy proposals.

An Bord Altranais, HIQA, the Irish Medicines Board and the Mental Health Commission have all undertaken consultations when developing standards or guidance documents. The Mental Health Commission undertook an extensive consultation exercise prior to the development of the standards that comprise its *Quality Framework for Mental Health Services* (2007). The views of service users, the general public and other key stakeholders were sought through consultation workshops, written submissions and focus groups. The results of this consultation exercise were published in *Quality in Mental Health: Your Views* (2005).

HIQA consulted extensively before publishing its *National Quality Standards: Residential Services for People with Disabilities.*[29] Members of the general public and other interested parties submitted feedback on published draft standards. In addition, focus groups were conducted with staff, service users and the families of service users at various locations throughout the country. Individual interviews were also held with service users for whom participation in a focus group was not a realistic option. An Bord Altranais consulted with the public and representative groups when developing a guidance document for nurses working with older people.[30]

The Inspectorate of Mental Health Services, which inspects mental health services in Ireland and reports to the Mental Health Commission, meets with local service user advocacy organisations such as the Irish Advocacy Network to inform its work. Comments received from these organisations are outlined in the Inspectorate's Annual Report.

Public views have also been sought on important policy proposals. In 2005, the Food Safety of Authority of Ireland sought the views of the general public and other interested parties on the possible fortification of food with folic acid to reduce the prevalence of Neural Tube Defects (NTDs) such as spina bifida.

By far the most common method of consultation used in Ireland is written consultations. However, member organisations also reported having used a number of other methods such as focus groups, information and communication technology (ICT), interviews, and public meetings.

D Representation on Governing Boards

The inclusion of public representatives on boards is now standard practice in most health and social care regulators in Ireland. Other regulatory boards include service user representatives. An Bord Altranais has two board members who represent the public interest and, they hold Board meetings on a bi-monthly basis that are open to nurses, midwives and members of the public. The Dental Council has two people who represent the interests of the general public as consumers of dental services as appointed by the Minister for Health and Children. Likewise, the Mental Health Commission includes one representative of the general public and 3 representatives of voluntary bodies promoting the interest of persons with mental illness (2 of whom must have or have had a mental illness).

Significantly, the traditional model of self regulation which characterised many professional regulatory bodies is being revised. Reforms have been made to the boards of some of these organisations in order to guard against the risks associated with self-regulation and clearly establish that the primary objective of such organisations is to protect the public. Irish reforms have led to the introduction of lay majorities to the boards of the Medical Council and the Pharmaceutical Society of Ireland through provisions of the Medical Practitioners Act 2007 and the Pharmacy Act 2007. Furthermore, the Health and Social Care Professionals Council was established with a lay majority in 2007.

E Representation on Advisory Groups
Regulators, including the Pharmaceutical Society of Ireland, HIQA, the Irish Medicines Board, the Medical Council, the Dental Council and the Pre-Hospital Emergency Care Council include service user or public representatives on Board committees or advisory groups. Working groups of the Medical Council include representatives from patient advocacy groups, employers and independent business people. Such working groups are directly involved with the development of professional competence guidance.

The FSAI has a consultative council which provides advice to the board of the FSAI on relevant matters. It is designed as a means for consumers and the food industry to provide input to the FSAI's agenda. Two of its 22 members are consumers and one is a representative of the Consumers Association of Ireland.

F Participation in Inspection and/or Review Activities
An Bord Altranais, the Irish Medicines Board, the Medical Council and the Mental Health Commission involve public or service user representatives when carrying out their inspection and/or review functions.

Members of the board of An Bord Altranais which include representatives of the public are part of the teams that conduct site visits to all healthcare institutions that are linked to nursing/midwifery education programmes at the Higher Education Institutes. A service user representative joined the inspection team of the Mental Health Commission in September 2008 and carries out the same functions as the other team members.

This chapter has illustrated the existence of a number of strategies that are used to involve service users and members of the public in the activities of Irish health and social care regulators. There is clearly an acceptance of the need for citizen engagement in the work of regulatory bodies. How Irish health and social care regulators fair by international standards is dealt with in the next chapter following a review of strategies employed in other countries.

3   The International Context

3.1   METHODS OTHER COUNTRIES ARE CURRENTLY USING TO INVOLVE THE PUBLIC & SERVICE USERS IN HEALTH AND SOCIAL CARE SERVICES

This section of the framework document describes some of the methods that are used in other countries to involve members of the public and service users in health and social care. Examples are drawn from the UK, Australia, New Zealand, United States, Canada, Finland, Sweden, Denmark and the Netherlands. Strategies that are used in the health and social care sector in general in these jurisdictions, as well as some of those used by regulatory agencies, are considered. It is not an exhaustive assessment of the extent of participation in these states but aims to highlight some good practice examples.

UK

The importance of involving service users in all aspects of healthcare started to influence UK government policy in the 1980's and was firmly enshrined there by the 1990's.[31] A number of strategies have been employed to maximise user involvement such as service user participation on the boards of Primary Care Trusts (PCTs) and regulatory bodies for instance.

Much of the UK government's efforts to involve service users and members of the public in health and social care occur at the local level. This strategy was outlined in the 2006 policy document, *A Stronger Local Voice*, and has been implemented primarily through the work of Local Involvement Networks (LINks) and Overview and Scrutiny Committees (OSCs).[32] Each LINk aims to be representative of the local community and is open to anyone to join. Networks have been established for every local authority with health and social care responsibilities and they are tasked with finding out the views of people in that area and holding the local authority, the NHS and any other health or social care providers to account.

An OSC is a local authority committee made up of elected councillors who are responsible for reviewing the local health services in the context of national regulations. LINks and OSCs work very closely together. One of the reasons for the local focus of *A Stronger Local Voice* is that "commissioning" i.e. determining how the health and healthcare budget is used, takes place locally. Eighty per cent of the National Health Service (NHS) budget is now devolved to locally based PCTs.

LINks have a number of key functions:

- To collect information to inform their work from a wide range of sources, including complaints, national patient surveys, user groups, focus groups;
- To be a means by which commissioners, OSCs and regulators such as the Care Quality Commission access the views of the local population; and
- To survey local health services. They have the power to enter and view specific types of premises where services and care are provided, ask for information and get a response within a specific timescale, make recommendations and get a response within a specific timescale and refer matters to the relevant OSC.

The role of OSCs is to examine the decision making activities of PCTs and local authorities. In particular, they are charged with establishing:

- Whether services are appropriate to the needs of local people;
- If decisions are based on evidence; and
- If the experiences of service users are leading to improvements in the delivery of services.

Primary care trusts are accountable to strategic health authorities (SHAs), and both LINks and OSCs can make formal representations to an SHA where they have concerns.

The National Institute for Health and Clinical Excellence (NICE) is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health in the UK. Service users, carers and other members of the public can become involved in NICE's work through its Patient and Public Involvement (PPI) programme. NICE has published a guide for patients and carers which outlines how they can contribute to clinical guidance, technology appraisal guidance, interventional procedures guidance and public health guidance[33]. One of the means by which patients and carers can contribute is by participating in the consultation phase of NICE's guideline development process. This occurs following the development of a draft guideline and lasts for 8 weeks. NICE always invites registered stakeholder organisations to participate. Any member of the public can also comment on a draft guideline although NICE states that comments from registered stakeholder organisations are likely to carry more weight. NICE also makes use of a 'Citizens Council' to inform its clinical guidance (See consultation framework, p44 for more details). Prior to the introduction of any new clinical guideline in Scotland, the Scottish Intercollegiate Guideline Network (SIGN) which carries out a similar role to NICE in Scotland holds a national open meeting to discuss the draft recommendations of each guideline.

Public involvement on committees in the UK also exists and the Nursing and Midwifery Council recently launched an advertising campaign to recruit public members to its committees.

The UK health and social care regulator, the Care Quality Commission, involves the public and service users extensively in its work. In addition to consultation exercises, it uses a range of other methods. It makes use of a national patient survey to provide it with feedback on patient experiences of health services. Surveys completed by users of services are also used during the Commission's inspection process for announced inspections. During announced and unannounced inspections, the Commission's inspector speaks to service users.

Strategies for involving service users and members of the public in health and social care can risk missing out on the views of people who are unorganized and do not belong to any voluntary or advocacy groups. For this reason, other social research methods that aim to elicit the views of more representative groups are used by the Care Quality Commission. It carries out special studies involving service users for instance. This includes reviews of services, which examine how patients with particular health conditions experience these services. To achieve this objective, the Commission usually invites service users to participate directly in the review, from the planning stage right through to inspection and assessment. Sometimes, the Commission works with service user organisations to recruit and train lay inspectors. It has carried out such work in the past with the mental health charity, MIND.

The Centre for Ethnicity and Health at the University of Central Lancahsire (UCLAN) also undertakes work on behalf of the Care Quality Commission that aims to engage people from minority groups. The university- based centre trains facilitators from minority groups who then organise local workshops and focus groups with other group members. This form of engagement is considered more likely to provide authentic feedback than identifying representatives to attend mainstream events.

Australia and New Zealand

The importance of consumer involvement in quality and safety activities in healthcare began to be recognised in Australia during the 1990's. Influential documents which recommended that this principle be recognised in national policy and practice were a 1996 report of the Taskforce on Quality in Australian Healthcare to the Australian Health Ministers' Advisory Council and the report of the National Expert Advisory Group on Safety and Quality in Australian Health Care (1999). As in Australia, this principle has since been enunciated in all major health and health related strategies in New Zealand including its Health Strategy (2000), Disability Strategy (2001) Primary Health Care Strategy (2001) and Youth Health: A Guide to Action (2002). This overlap extends to the work of healthcare accrediting organisations. Quality Health New Zealand, a New Zealand accrediting organisation, makes use of standards derived from those of the Australian Council for Healthcare Standards (ACHS).

From a regulatory perspective, one of the methods used in Australia has been the inclusion of service users on inspection teams. A successful pilot study in 2001 showed that using service users as inspectors could add real value to an accreditation survey. Following this, the healthcare accrediting agency, the Australian Council for Healthcare Standards (ACHS), began using "consumer surveyors" in a number of settings. This has included "In-depth reviews" (IDRs) of mental health services. These reviews use both consumer and health professional surveyors to assess mental health services against National Mental Health Standards within a quality improvement framework. Surveyors are allocated a number of days to assess each mental health service for aspects of care identified in the standards.[34] One area that is given particular focus in the standards is service user and public participation and acceptability.

A further Australian initiative in the healthcare area includes consumers on the quality improvement committees of healthcare facilities that are seeking accreditation. Such a committee will usually co-ordinate preparations at a healthcare facility before and during the accreditation process. This can include producing self-assessments, reports and other materials required by the accrediting organisation. A quality improvement committee will also usually play an active role during accreditation visits. A consumer member of such a committee should voice the consumer perspective and take part in the decision making process on behalf of consumers. Such members will usually be nominated by and be accountable to consumer representative organisations.

As Australian practice has moved away from viewing accreditation as a once-off process that happens only every few years, accreditation agencies now carry out more regular reviews of services and look at documented efforts to improve quality over time, rather than just focussing on the standards in a service during accreditation visits. To reflect this change in focus, quality improvement committees are now also involved in continual quality improvement processes.[35]

Community control of healthcare in Australia is a feature of a number of health services for Aboriginal communities. Community control occurs when the community elects a board that is responsible for the management of the health service. Like management roles elsewhere, the board determines the health service's goals, objectives and priorities. Community control means that the service's management must ensure that the community and service users are involved in all decisions of the service, it is not optional.[36]

An example of a community controlled health service is the Nganampa Health Council in South Australia. It is a comprehensive primary health care service that runs programmes in aged care, sexual health, environmental health, health worker training, dental care, women's health, male health, children's health and substance abuse prevention. In the 20 years of its existence, the council has achieved measurable health improvements for the local community, especially in the areas of child and maternal health.[37]

In New Zealand, the work of the Health and Disability Commissioner, whose role is to promote and protect the rights of consumers who use health and disability services is informed by the work of a Consumer Advisory Group. In addition to health and disability representatives, it also includes representatives of Pacific and Maori groups.

United States
The federal political system in the United States means that regulatory functions take place at both the state and federal level. As a result, the regulatory landscape differs from state to state.

The US Food and Drug Administration (FDA) operates a Patient Representative Programme to enable patients who have or have had a serious or life-threatening illness to bring their perspective to FDA Advisory Committees. Sometimes, a patient supporter such as a parent or carer may serve as a representative. Advisory committees are established to assist the FDA to arrive at decisions in relation to new drugs, biologics, medical devices, and other public health issues.[38] Patient Representatives are usually voting members of such committees when the committee is reviewing a non-medical device, otherwise they are non-voting members. Apart from having personal experience with a specific serious disease, other selection criteria for the programme include experience in patient advocacy and an ability to understand scientific data and technical information about research studies.

Other regulatory advisory groups consist entirely of service users and/or members of the public. For example, in addition to having lay membership on its board, the healthcare accreditation organisation, the Joint Commission, has a separate Patient and Family Advisory Group on Health Care Quality. The 20 member group was established to help the Joint Commission define public expectations for quality in health care and to offer its advice and recommendations on introducing improvements to the accreditation process.

The Joint Commission and another accreditation organisation, the Commission on Accreditation of Rehabilitation Facilities (CARF), actively seek patient and consumer feedback during accreditation surveys. Both organisations require health and social care facilities to place public notices in their buildings announcing that a survey will shortly take place. Such notices invite consumers, employees and other interested parties to offer feedback on the quality of care and safety of the care environment. In a healthcare facility seeking Joint Commission accreditation, people can request a Public Information Interview with one of the surveyors.

Invitations to submit comments using other methods, including by telephone, email and web feedback form are also issued. All feedback that CARF receives from these methods is forwarded to the relevant inspection team prior to the inspection. The team considers these comments as it inspects the facility using its standards and may contact some of the respondents for further information or clarification.

Canada
Over the last 10 years, governments across Canada have begun embracing a *"citizen-centred"* approach to public service delivery. The public sector has been shifting from an internally-focused *"inside out"* perspective to an increasingly *"outside-in"* perspective when delivering service to the public, where the interests and opinions of citizens are instrumental in defining expectations, setting priorities, and establishing service standards.

The Institute for Citizen-centred Service which is a non profit organisation was set up in 2005 to promote high levels of citizen satisfaction with public sector service delivery. The inter-governmental Citizen-Centred Service Network (CCSN) released a series of reports, tools and recommendations for improving citizen satisfaction with public sector service delivery in Canada. This included the Citizens First study (published in 1998) which was a landmark step in this process where Canadians across the country were asked what they thought about the delivery of public services, what expectations they held, and what they saw as the priorities for improvement. It also included the electronic common measurement tool (CMT), which is an easy to use client satisfaction survey; and a database in good practice service delivery. One of the issues emerging from the Citizen First Study was the problem of citizens needing to contact multiple government offices for a single service issue particularly around certificates, licenses and registration. As result, Service Canada was established in 2005 as a 'one stop' delivery network providing access to over 77 different government programmes.

A National Forum on Health, an advisory body, was established in 1994 as a means of effectively involving individuals and key stakeholders in the Canadian healthcare system. The forum advised federal government on innovative ways to improve Canada's health system and the health of Canadians. In 1997, it published a report "Canadian Health Action: Building the Legacy", which emphasised the importance of accessible information through state of the art technology. The government of Canada is also committed to public involvement in the development of government policies and programs and in this regard includes how the public have been consulted on any initiatives on all memorandums to Cabinet. This mirrors the recent recommendation of the Commission on Patient Safety and Quality Assurance in Ireland.

In terms of professional regulation, unlike Ireland, professional health regulation is structured so that licensing and regulation is carried out at provincial and territorial government level in Canada. The Provinces and Territories usually delegate control over health professions to professional colleges, who set standards, license practitioners and deal with complaints.[39] Each College of a health profession is required by the Health Professions Procedural Code (Sec. 84 (1)) to have a Patient Relations Program, which is defined in the Code as *"a program to enhance relations between members and patients".* Colleges are also required to have a Patient Relations Committee under the Regulated Health Professions Act. The Health Professions Regulatory Advisory Council has the responsibility to monitor the Colleges' Patient Relations Programs, and to advise the Minister of Health and Long-Term Care about their effectiveness. Accordingly, Colleges have the obligation to establish strategic goals, standards and directions to ensure a strong patient relations' focus.

Sweden, Finland, Denmark & the Netherlands
Scandinavian countries have some of the best healthcare system in the world with very high levels of customer satisfaction with health and social care services. For example, Finland is ranked 2nd out of 28 European countries in a combined index of satisfaction with health and social care services despite healthcare spending per capita being amongst the lowest of OECD countries. Denmark is ranked 5th out of 28 countries.

Sweden's healthcare system is characterised by high levels of citizen empowerment. Service users have good access to large amounts of information about healthcare and have a right to choose where to have treatment. Devolution of healthcare in Sweden to local and regional government has lead to healthcare being organised according to the needs of local residents rather than at national level. From a regulatory perspective, at national level there exists a number of organisations including the Board of Health & Welfare, the Medical Responsibility Board, the Swedish Council on Technology Assessment in Health Care, the Pharmaceutical Benefits Board and the Medical Products Agency. The National Board of Health & Welfare, which has many different duties within the fields of social services, health and medical services, environmental health, communicable disease prevention and control and epidemiology, produce a report of healthcare performance across the country every year. Two of the committee members on the Pharmaceutical Benefits Board, which regulates the pricing of medicines, are from service user groups.

Like Sweden, Finland is divided into self-governing municipalities, which are autonomous and responsible for providing health and social care services amongst other things. In terms of citizen empowerment, the most important channel for the public to participate in the health system is through locally elected municipal authorities allowing communities, amongst other things, exercise preference over spending priorities.[40] The State undertook major regulatory reform in 1993 and dismantled the National Board of Health, which regulated healthcare, moving towards a policy of *"guidance by information"*.[41] Patient complaints are collected together as part of Finland's national policy of *"steering by information"* and patients have a right to information. There are a few state agencies with regulatory functions in Finland, such as the National Agency for Medicines (NAM) and the National Authority for Medico-legal affairs, the latter of which was subsumed this year into the National Supervisory Authority for Welfare & Health.

One initiative in Denmark is that of the 'Danmarks Debatten', which is an online discussion forum designed to allow citizens and elected representatives including local authorities and other government bodies to instigate debate around current issues facing citizens in a locality.

In terms of public services, the Netherlands recently introduced an e-citizen charter which sets out how citizens can expect to be treated, such as rights to interact with services through a choice of channel and rights to accessible performance information. The ten principles of quality are formulated as rights of citizens. A programme called "Citizenlink" with a 'Peoples Panel', and online discussion boards support enforcement of the charter.[42]

Lastly, from a European perspective, the European Medicines Agency (EMEA) is very active in its interaction with patients and consumers. It includes interaction with a range of international patient organisations. Activities include a designated Working Party with Patients' and Consumers' Organisations (more commonly known as the Patients' and Consumers' Working Party, or PCWP) which was established to provide recommendations to the EMEA and its human scientific committees on all matters of interest to patients in relation to medicinal products. Details of the membership, recommendations, guidance documents, and minutes of meetings are all available on the EMEA website (see http://www.emea.europa.eu/).

3.2 IRISH STRATEGIES FOR PUBLIC/SERVICE USER INVOLVEMENT IN HEALTH AND SOCIAL CARE REGULATION IN AN INTERNATIONAL CONTEXT

This section assesses Irish strategies to involve members of the public and service users in an international context. After noting some good practice examples from other countries, some similarities and differences between Irish and international practice, are now identified.

All of the main strategies that are used by Irish health and social care regulators to involve service users and the public are also used internationally. Examples of information provision, consultation during the development of standards and involvement in governance were evident in Ireland and in other states.

However, some differences can be discerned between Irish and international practices in terms of how some strategies are operationalised. For instance, consultation related to inspection and review activities typically takes place in Ireland after the inspection of a healthcare facility. In the United States, efforts are made to encourage public and service user feedback before and during inspections.

Other international strategies emerged that are not used by Irish health and social care regulators. These include community focussed involvement strategies such as Finnish participation in health and social services that is channelled through locally elected municipal authorities. Participation at a local level also takes place in the UK through its Local Involvement Networks and Overview and Scrutiny Committees. In addition, there is no Irish equivalent of the NICE Citizen's Council in the UK or the Patient Representative Programme that is operated by the FDA in the United States.

The local focus of public participation in Finland and the UK is clearly linked to features of their political systems and specifically the fact that much of the health budget in these states is devolved locally. Nevertheless, such local forums illustrate effective methods for involving citizens in health and social care services which Irish regulatory bodies could learn from. When service users and members of the public become involved in the work of Irish regulatory bodies, it usually occurs at a national level.

Examples of strategies that involve the public and service users to varying degrees were observed in Ireland and in other states. Irish strategies that involve members of the public such as public consultation initiatives do not lend themselves to ensuring that the views of a wide range of people are heard. Typically, people who are actively involved in representative and advocacy groups and those with a particular interest in specific health and social care issues become involved in such initiatives. Conversely, NICE's Citizen's Council and the Care Quality Commission's use of focus groups for minority groups are examples of strategies for involving seldom heard groups. Strategies such as including members of the public and service users on inspection and review teams on the other hand are specifically designed to ensure that the public/service users do have a direct influence on regulatory activities. Chapter 4 introduces a framework for public and service user involvement in regulation which aims to involve the public and service users at different levels in the work of regulatory bodies.

Directions for the Future

4.1 FRAMEWORK FOR PUBLIC/SERVICE USER INVOLVEMENT IN HEALTH AND SOCIAL CARE REGULATION

As evident in Chapters 2 and 3, there are different degrees to which the public and service users can be involved in health and social care services and in the regulation of these services. By international standards, Ireland fairs reasonably well in terms of the strategies adopted to involve the public and service users in the work of regulatory bodies to date.
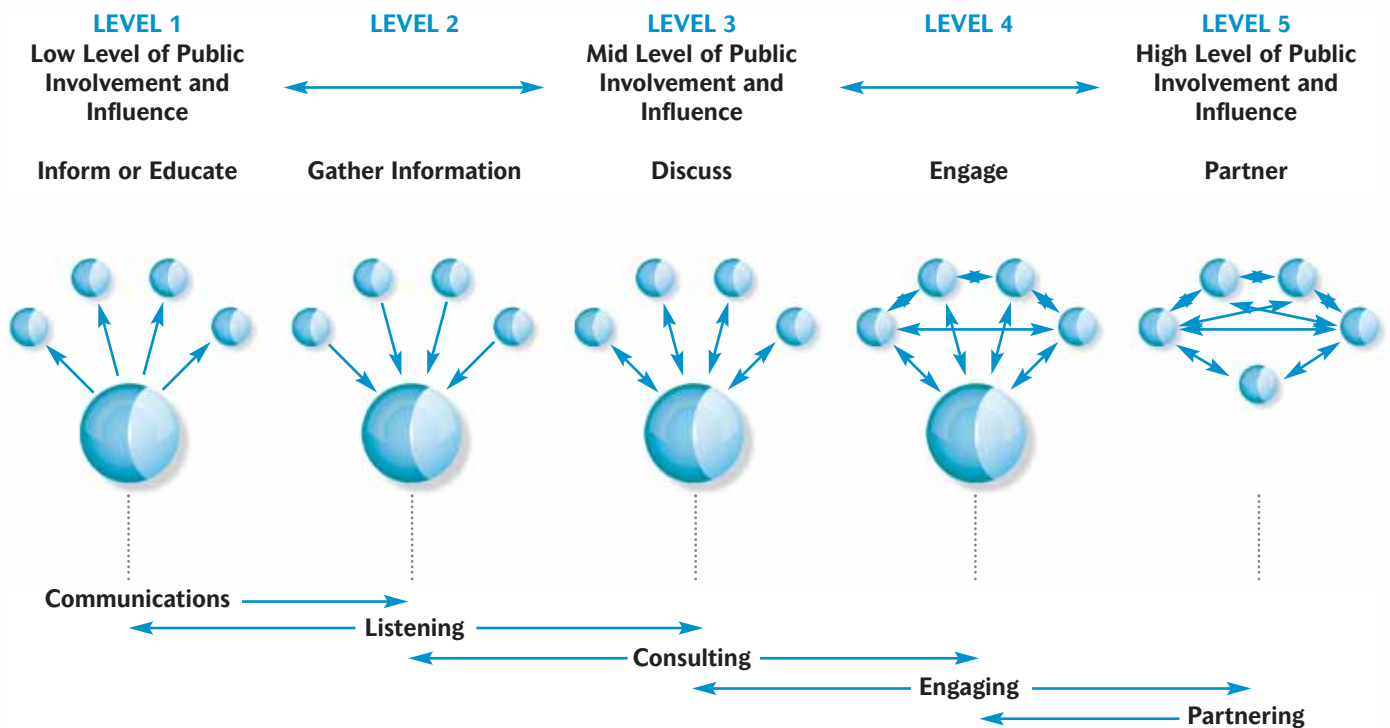
However, as highlighted in the last chapter, some of the countries with the best public services and indeed healthcare systems in the world have very high levels of citizen empowerment, where public services strive to be truly personalised and power to shape those services is put as close to the individual citizen as possible. This is something which Ireland has made some progress on in the past but as highlighted by the OECD Ireland needs to extend the customer focus *"beyond narrowly defined customer service initiatives to all aspects of the work of the public service"*.[43]

The following framework breaks public and service involvement down into five levels (see figure 1 below), with level one being considered a low level of involvement compared to activities in Levels 4 and 5 which indicate a high degree of public involvement and influence.[44] Under each level, is listed a number of strategies which typically represent that level of involvement. Examples and good practice initiatives are provided to facilitate operationalisation of a strategy. The line between levels and the methods placed under each level is, however, drawn somewhat arbitrarily in that true level of involvement and influence can really only be determined by evaluating the success of the method employed and whether the public and service users voices' have been heard as emphasised in Section 4.2. Generally speaking, as an organisation moves up the levels, public and service user involvement in the organisation's work should deepen.

All regulatory bodies should ultimately be striving for levels 4 to 5 involvement in their organisation where service users and the public are engaged in and are partners in the three pivotal elements of regulation identified in chapter 1 (box 1.0) i.e. direction, surveillance and enforcement.

Before deciding on a strategy, it is important to consider **the purpose** of public or service user involvement in an exercise, for example, it may be to inform/educate, discuss through two-way dialogue, fully engage on complex issues or partner in the implementation of solutions. It may also be appropriately to combine strategies having regard to objectives and available resources.

Figure 1 - Framework for Public & Service User Involvement in Regulation

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Low Level of Public Involvement and Influence		Mid Level of Public Involvement and Influence		High Level of Public Involvement and Influence
Inform or Educate	Gather Information	Discuss	Engage	Partner

Communications — Listening — Consulting — Engaging — Partnering

Adapted from Patterson Kirk Wallace, as cited in Health Canada's (2000) *Policy Toolkit for Public Involvement in Decision-making*, p.12.

LEVEL 1: COMMUNICATE

A COMMITMENT TO CITIZENS

Commitment at all levels of the organisation to service user involvement is one of the recommendations of the National Strategy for Service User Involvement in the Irish Health Service. Examples of this include:

- *Customer Charters:* A customer charter is a short synopsis of how customers will be treated and informing them of complaint and redress mechanisms. All public service organisations are required to have a customer charter in place since 2002.The Task Force in the Public Service (2008) recommends that public bodies review customer charters and, where appropriate, containing strengthened service commitments to customers and meaningful output-based performance metrics.[45]

- All policies, plans, standards, rules and codes of practice should be accompanied by a statement of how service users/the public were involved in the development process.[46]

Some Good Practice Initiatives:

- See Care Quality Commission's website in the UK Section "Get Involved", which demonstrates a clear commitment to public and service user involvement - http://www.cqc.org.uk/getinvolved.cfm.
- See Mental Health Commission. Customer Charter - http://www.mhcirl.ie.
- E-Citizen charter. See the Netherlands e-charter - http://www.burgerlink.nl/englishsite/englishsite.html.

B INFORMATION PROVISION & EDUCATION

The Report of the Commission on Patient Safety & Quality Assurance highlights the importance of having knowledgeable individuals. All regulatory bodies should provide service users and the public with clear, accurate and timely information. Information should be easily accessible and in a variety of formats.[47] Examples of methods by which information can be provided include the following:

- Website
- Press releases
- Mail outs
- Fact sheets
- Single window access to public services information

Some Good Practice Initiatives:

- See the Council for Healthcare Regulatory Excellence, Public Stakeholder Network - http://www.chre.org.uk/public/.
- The Health & Disability Commissioner, New Zealand, publish website hits per month in their annual report - http://www.hdc.org.nz/files/hdc/publications/annual-report-website08.pdf.
- See HIQA National Quality Standards documents - http://www.hiqa.ie and the Mental Health Commission's Service User Guide to the Mental Health Act 2001, www.mhcirl.ie for examples of plain English and easy read versions of documents produced.
- Publishing a joint catalogue of the different services regulatory bodies offer to the various groups so that citizens whose shared needs require the efforts of a number of public bodies can access information in the one place [48] - See Service Canada 'One stop' delivery network, Canada - http://www.servicecanada.gc.ca/eng/home.shtml. See also information leaflet on Health & Social Care Professionals UK - http://www.rpsgb.org.uk/pdfs/regulatorsleafleten.pdf.

LEVEL 2: LISTEN

C COMPLAINTS AND CUSTOMER-FOCUS SCRUTINY

Complaints, comments, and satisfaction surveys are increasingly being used as a useful source of quality information on the public's and service users' experiences of services. These can be used to ascertain the views and satisfaction of individuals who have experienced services, for example experience of inpatient services, emergency services and primary care services. The information yielded from complaints, for example, can be used as an opportunity to promote service user satisfaction by responding in a timely and sensitive manner to grievances. Examples of strategies falling under this heading include:

- National Patient Surveys
- Customer Satisfaction Surveys
- Feedback and Complaints systems

Some Good Practice Initiatives:

- Quantitative surveys of Patient Opinions. See the Care and Quality Commission in the UK - http://www.cqc.org.uk.
- Client satisfaction surveys. See Institute for Citizen-Centred service in Canada - http://www.iccs-isac.org.

D   PUBLISHING PERFORMANCE RESULTS

Surveillance is a key regulatory function where an organisation's performance is assessed and compliance is monitored with standards, targets and regulations. In this regard, publishing information on how health and social care services are performing is an important part of openness and transparency by enabling both the public and service users to review service quality and determine which organisations are performing well.

Some Good Practice Initiatives:

- See Annual Health Checks by the Quality Care Commission in the UK - http://www.cqc.org.uk.
- See Healthcare Quality and Efficiency Reports produced by the National Board of Health & Welfare in Sweden - http://www.socialstyrelsen.se/en.
- See HIQA - http://www.hiqa.ie and the Mental Health Commission's http://wwwwww.mhcirl.ie annual inspection reports published on their websites.

LEVEL 3: CONSULT

E   CONSULTATION EXERCISES

Consultation refers to initiatives to listen to and take on board the views of stakeholders and the general public, through requests for feedback on different issues. Consultation is a long standing method of public and service user involvement in Irish public services. It is a key means by which the views of the public and service users can shape the work of regulatory agencies such as the development of standards, codes of practice, rules and regulations. Consultation can also take place before and during inspection and review processes where inspection teams actively seeks the views of service users and members the public. An inspection can be more fully informed where feedback is received before an inspection. This can be achieved by publicising an inspection in the healthcare/social care facility beforehand and inviting feedback from service users/members of the public.

Some Good Practice Initiatives:

- A framework for public consultation is provided in Appendix 1.
- Citizen councils, See NICE in the UK - http://www.nice.org.uk.
- National public meetings, See SIGN in the UK - http://www.sign.ac.uk.
- Consultation relating to inspections/reviews. See the Commission on Accreditation of Rehabilitation Facilities in the United States - http://www.carf.org.
- Consulting with Young People. Development of the Headspace toolkit by Advocacy in Somerset UK - http://www.headspacetoolkito.org.

LEVEL 4: ENGAGE

F   LOCAL INVOLVEMENT STRATEGIES

Local involvement strategies are methods of involving people in health and social care at the local or community level. An example of such a strategy is the UK strategy of making health and social care organisations accountable to locally elected councils or groups containing members of the public from the community in which the healthcare or social care organisations operate.

Community forums also operate at the local level. They are like focus groups but involve a larger group of service users and can be a useful way for organisations to hear the experiences of people in the community. Additionally, online forums are increasingly being used in other countries whereby members of the public can engage directly with local elected representatives to give their views and experiences of public services.

Some Good Practice Initiatives:

- See the UK Local Involvement Networks and Overview and Scrutiny Committees - http://www.direct.gov.uk/en/HealthAndWellBeing/HealthServices/PractitionersAndServices/DG_071867.
- See "Danmarks Debatten" online forum in Denmark - http://www.danmarksdebatten.dk.
- See Citizenlink programme in the Netherlands - http://www.burgerlink.nl/englishsite/englishsite.html.

G   REGULATORY ADVISORY GROUPS

A regulatory advisory group is a group or committee which is set up to provide comments and advice to a regulatory body. There can be service user and/or public representation on the advisory group or it can be wholly composed of members of the public and/or service user representatives. In both cases, the representatives are tasked with outlining the service user and/or public perspective.

Where such a group includes service user/public representation, it is important to ensure that the full range of service user/public interests and values is represented, that the group's role in decision making is clarified and that sufficient time is provided for members to maintain communication with their constituencies and ensure that public and/or service user views are adequately represented.[49]

Some Good Practice Initiatives:

- See the Food Safety Authority of Ireland's Consultative Council - http://www.fsai.ie/about_us/consultative_council.html.
- See the FDA Patient Representative Programme that operates in the United States - http://www.fda.gov.
- See also the Joint Commission's Patient and Family Advisory Group in the United States - http://www.jointcommission.org/AboutUs/public_advisory_group.htm.

LEVEL 5: PARTNER

H INTRODUCING REPRESENTATIVES TO INSPECTION/REVIEW TEAMS

This involves introducing a public and/or service user representative to the inspection or review team of a regulatory body. Any public or service user representative is an equal member of the inspection team who brings his/her own experience to the inspection process. An Australian resource guide outlines a number of additional considerations for organisations who are considering using service users or members of the public as "surveyors".[50]

Some Good Practice Initiatives:

- See example in the Mental Health Commission's Inspectorate of Mental Health Services.
- See the Australian Council for Healthcare Standards - http://www.achs.org.au.

I INVOLVEMENT IN THE GOVERNANCE OF REGULATORY BODIES

This involves placing service users and/or members of the public on the decision making boards of regulatory organisations. This already occurs in most forum member organisations. Public and service user representatives on the boards of regulatory bodies in the health and social care area are usually selected by the Minister for Health and Children. Such representatives will often have links with an established advocacy/representative organisation.

Some Good Practice Initiatives:

- Many Irish professional regulatory bodies now have lay majorities on their boards. See the Medical Council - http://www.medicalcouncil.ie.
- Good practice guidance on public involvement on the boards of public organisations can be found in the Health Canada Policy Toolkit for Public Involvement in Decision Making - http://www.hc-sc.gc.ca/ahc-asc/pubs/_public-consult/2000decision/index-eng.php.

4.2 EVALUATING LEVEL OF INVOLVEMENT & STRATEGIES

An important feature when determining true level of involvement having used a particular strategy, is evaluating the success of that strategy.

The adoption of a strategy does not in itself guarantee that level of involvement and influence alone. For example, consulting with the public or service users does not in itself mean that their views have been taken on board in the regulatory activity. Similarly, where service users or public representatives exist on the board of a regulatory body, it is still possible that professionals have more influence on governing bodies than their weight in numbers.

Where any of methods outlined in Section 4.1 are used by regulatory bodies, it is especially important that an evaluation is carried out to assess the extent to which the desired level of service user and public involvement has actually been achieved.

Similarly, the use of a strategy or method needs to be accompanied by particular measures which enhance the ability of the strategy or method to deliver involvement and influence. For example, it is good practice to publish the findings of public consultations, summarising key themes and outlining actions that will be taken by the organisation as a result of feedback received (See Framework for Public Consultation in Appendix 1 for more information).

4.3 ENABLING FULL AND EFFECTIVE PARTICIPATION

Public and service user representation is likely to be more effective if representatives are enabled to participate more fully. In particular, the following should all be considered:

- Adequate training is provided where required, especially for representatives who are members of advisory groups or boards;
- Representatives are given sufficient time to consult with their constituencies; and
- Representatives are paid or reimbursed in some other way, where appropriate.

4.4 PROGRESSING PUBLIC/SERVICE USER INVOLVEMENT IN HEALTH & SOCIAL CARE REGULATION IN IRELAND [JJ]

Following endorsement of the report, each member organisation of the Forum is committed, as appropriate to the functions and resources of the organisation, to:-

- Undertake an evaluation of the level at which they currently involve the public and service users in their organisation. Part of this step was the initial completion of the questionnaire dealt with in chapter 2. The ISQSH & HCI (2009) toolkit for public and patient involvement in healthcare includes a self assessment evaluation tool which could be used for this purpose [51] (See Appendix 3);

- Apply the consultation standards identified in the public consultation framework in Appendix 1 and agree to co-ordinate, where appropriate and possible, on consultation exercises. This was proposed as a means of demonstrating continuous learning and ongoing commitment to excellence among Forum members;

- Recognising that facilitation and engagement work requires a specialised skill base. Each member organisation will share information on staff training and capacity-building in this area to promote the use of best practice methods across the health and social care sector.

- Including information on their performance relating to public and service involvement in their annual report as a means of providing all stakeholders, but most especially the public and service-users with a better understanding of the variety of ways in which they can become involved across the work of the respective organisations.

[JJ]   *The Council for Healthcare Regulatory Excellence in the UK has developed a plan for 2009 as to how they will work with patients and the public, which identifies four key aims and timelines for implementation. This plan may also provide the forum with further direction in terms of implementation of the framework.*

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Appendices

Appendix 1: Draft Public Consultation Framework

INTRODUCTION

This paper outlines a draft consultation framework prepared by the Mental Health Commission, which may be of interest to the Forum of Health and Social Care Regulators with regards to public consultation in the context of health and social care regulation. Since a core function of regulatory bodies is to develop appropriate rules, standards and guidance that serve the public interest, such bodies should recognise that these provisions are better-informed, more rigorous and accountable where their development has been assisted by a phase of public consultation.

Consultation refers to initiatives to listen to and take on board the views of stakeholders and the general public, through requests for feedback on different issues. It is a two-way conversation between an organisation and its stakeholders and members of the public, which should ensure that stakeholders and the public are in a very real way participating in an organisation's decision-making and policy-making activities.

Among the benefits of consultation to an organisation are:[52]

- It strengthens the focus of the organisation on the needs of its stakeholders and fosters a working partnership which contributes to a shared understanding of issues and encourages work towards agreed solutions;
- It assists the decision-making process by ensuring that interested parties can express their views on a particular code, set of rules, standards or other draft document;
- It helps to gather useful information to inform the evidence base for making regulations or codes of practice;
- It helps an organisation to set performance standards that are relevant to stakeholder needs;
- It supports the rationale for a proposal as well as identifying the likely pitfalls or possible unintended consequences of a proposal so there is a chance to intervene and make amendments; and
- It symbolises a commitment to be open and accountable.

There are a number of comprehensive general consultation guidelines and handbooks, from both national and international sources, which provide recommendations as to how best to consult with stakeholders. These include *Reaching Out: Guidelines on Consultations for Public Sector Bodies* (Department of the Taoiseach, 2005), *Citizens as Partners: OECD Handbook on Information, Consultation and Public Participation in Policy Making Guide* by the Organisation for Economic Co-operation and Development's (OECD, 2001) and the UK Cabinet Office's introductory guide to consultations, *How to Consult Your Users* (2004). The Health Information and Quality Authority (HIQA) has also produced an internal Guide to Consultation and the National Disability Authority (NDA) has published the *Ask Me Guidelines for Effective Consultation* (2002), which contains specific recommendations for the carrying out of consultations with people with disabilities.

Several of these documents have been used to inform the consultation framework proposed in this paper.

FRAMEWORK

This consultation framework is structured into three key stages which are adapted from the Department of the Taoiseach's guidelines (See Figure 1 below):
A. Planning;
B. Execution, and
C. Analysis & Evaluation.

Each stage is in turn composed of a set of actions which should be carried out during each consultation. While each stage is therefore prescriptive, the framework also contains sufficient flexibility to enable an organisation to manage consultation exercises in different ways to suit a project's particular circumstances.

PLANNING

Subject and purpose of consultation

- What is the consultation about?
- What will the consultation achieve?

Identification of timescales and questions for consultation

- What is the scope of the consultation?
- How long will it last?
- What questions need to be answered?

Identification of stakeholders and methods

- Who should be consulted?
- What is the best way of reaching them?
- Will your chosen methods reach everybody?

EXECUTION

Decision to proceed

- Will the chosen channels reach everybody?
- Is the material accessible?
- Have you considered legal obligations?

Publication and distribution of material

- Have you chosen channels that will reach everybody?
- Is the material accessible?
- Do stakeholders have enough time to respond?

Consultation period

ANALYSIS & EVALUATION

Analysis of responses and dissemination of results

- Will submissions be published?
- Will the analysis draw out key messages and themes?
- How will feedback be given?
- Will you need help to do analysis?
- Will another consultation round be required?

Review of consultation process

- What worked and did not work in the consultation?
- How will lessons be disseminated?
- Did the consultation make a difference?

The stages and key actions which comprise the proposed framework are set out below.

A   PLANNING

It is vital that advance planning takes place to ensure that every consultation exercise proceeds in the best way possible. This involves, amongst other things, an identification of the aims of the consultation exercise, the length of time the consultation should last and the relevant organisations and people whose feedback it is vital to receive on a particular code of practice, set of standards or other initiative. With this in mind, organisations should be committed to the following actions.

- **Building consultation into the organisation's regular planning cycle and consulting early.**
  Agencies should plan consultations as far in advance as possible by integrating them into their business plans.

  By consulting early, changes can be made to an initiative that may not be possible where people's views are sought later on in the policy development process.

- **Developing a consultation plan for each consultation process.**
  Any member(s) of staff within an organisation planning a consultation should develop a consultation plan (See appendix 1 for template). As part of this plan, the following areas should be addressed.

2(a) Define the subject, purpose and objectives of the consultation exercise.

When setting aims or objectives for a consultation exercise, an organisation should identify SMART objectives i.e. Specific, Measurable, Agreed, Realistic and Time-Bound. Most consultations aim to elicit feedback on the content of a proposed code, set of standards or rules, but there may also be supplementary aims which a consultation strives to achieve. For instance, the Mental Health Commission's recent consultation with stakeholders on the Draft Code of Practice on Admission, Transfer and Discharge from Approved Centres included an implementation impact analysis, which aimed to identify potential benefits, costs and challenges of implementing the draft code of practice as well as obtaining feedback on the content of the code itself.

A clear understanding of the purpose and objectives of a consultation will also help determine who should be consulted, the most appropriate method by which they should be consulted and the appropriate timeframes for consultation.

2(b) Identify the stakeholders who should be consulted.

Each agency should maintain a database of key stakeholders. This is a vital resource which should be drawn upon each time a formal consultation is being undertaken. It is important that such a database is continually reviewed, updated and expanded as required. Stakeholder organisations, especially in the NGO sector change very quickly. A person with designated responsibility for a stakeholder database should be assigned in each organisation.

Specific Groups - e.g. Young people, people living in poverty

Consideration should be given as to whether there are other persons and organisations that are likely to be affected by a proposal and who are therefore particularly relevant to a consultation. This is important so that less visible and hard-to-reach groups that do not already have a relationship with the agency are not overlooked. The Department of the Taoiseach guidelines suggest making use of tools such as Regulatory Impact Analysis to identify hard-to-reach groups.

It is important that young people are provided with an opportunity to contribute to initiatives affecting them. In this regard, creative approaches are required to ensure that their voices are heard. The National Children's Advisory Council issued policy recommendations to the Minister for Children a few years ago on how best to build effective structures to consult with children and young people.[53] These recommendations included encouraging youth-led participation, acknowledging the important input of voluntary organisations, and that the National Children's Office should progress initiatives in relation to consultation processes for young people. The Ombudsman for Children, for example, has a youth advisory panel (YAP), comprising a group of young people that advises the Ombudsman on issues affecting young people in Ireland today. Similarly, Headstrong, a charity aimed at supporting young people to achieve positive mental health and well-being have a YAP, which acts in an advisory capacity to the organisation. The Surrey Children's Fund in the UK developed a participation toolkit for involving young people in decision-making in 2006 which may be of assistance when planning a consultation with young people.[54]

The Department of Health and Children in the consultation exercises it undertook when formulating the health strategy, "Quality and Fairness - A Health System for You", used the structures of the National Anti-Poverty Strategy to ensure that the views of people living in poverty contributed to the final strategy.

A list of all the groups, organisations and representative bodies to whom consultation invitations have been issued can also be appended to all consultation documents accompanied by a general invitation to invitees to identify additional relevant organisations that may have been overlooked in the consultation. This is standard practice in the UK Department of Health when it undertakes written consultations.

Internal Stakeholders
The OECD's handbook on consultation also stresses the advantages accruing to organisations who involve their staff as much as possible in consultations.[55] Organisations should operate an open and engaging process to consultations internally as well as externally. Potential internal stakeholders are identified early in the development process of a new policy initiative and their views are actively sought as part of the development process.

2(c) Identify the appropriate methods to achieve the objectives of the consultation and to reach the stakeholders who have been identified.
Each agency should strive to employ a mixed-methods approach to consultation as this is the preferred approach recommended in numerous guideline documents.[56] Using a mixed methods approach increases the likelihood of receiving a larger number of responses from a more diverse range of stakeholders. It is important as part of this approach to adapt the methods chosen to fit the circumstances of the consultation. Information on some common consultation methods, as identified in the literature, is provided to facilitate selection of the most appropriate methods for a particular project.

Written Consultations
Written consultation is the dominant means by which government and statutory agencies consult in Ireland. The main advantage of this approach is that it gives stakeholders an opportunity to consider an issue in depth and to put forward all of their views on a particular proposal in a structured manner. This document provides a checklist in the execution stage (Pages 47-48) on important areas to address in written consultations.

However, written consultations should not be used as the default option as over-reliance on this method is likely to exclude certain people from the process e.g. some people with disabilities and those who experience literacy difficulties.[57]

A means of partially overcoming this problem is through production of alternative versions of a consultation document, including an audio version, a Plain English version, an Easy-to-Read version and a Braille version. This has both budgetary and timing implications which should be considered and resolved at the planning stage.[58]

Because of these issues, where written consultations take place, other consultation methods that are highlighted below should also be used.

Open Space[59]
Open Space involves bringing together the group(s) to be consulted with and facilitating group feedback sessions at a consultation event. It requires more staff input on the day of the event than other consultation methods but is a quick and very effective means of collecting a large and broad range of views.
The main advantage of this method for stakeholders is that it reduces the amount of time required of them. It requires one day's participation which places less of a burden on stakeholder organisations than that required in the case of a written consultation.

Round-table Sessions
Round-table sessions involve holding a series of round-table discussions with the groups who are to be consulted with. They are smaller events than Open Space. Sometimes, all consultees cannot be brought together in a single group where an issue under consultation is particularly sensitive for example or if the groups in question are so diverse so as to make it impractical for them to come together in a single group. A different round table session can be held with each group.

Polling
Polling mainly involves the use of telephone or online surveys to access the views of a representative sample of members of the public. In order to be robust, any survey has to have a minimum sample of 1000, randomly-selected adults.

Omnibus polls and surveys involve the use of an external specialist organisation and so the cost implications are to be considered at budgetary planning stage.

Focus Groups
Focus groups entail a facilitated discussion among a small group of people in a one–off discussion on a particular topic. They allow the exploration of issues in depth and are a particularly valuable tool when an organisation wishes to obtain the views of a particular group of people on a proposal. It is recommended that a trained external facilitator is used to avoid the impression that an organisation is setting and driving an agenda.

Face-to-face Interviews

Face-to-face interviews allow a thorough examination of a proposal to be carried out with stakeholders and are an especially useful tool for obtaining information from key informants. Such interviews should produce a large amount of qualitative data. Where a large number of face-to-face interviews need to be carried out however, they can increase the time period necessary for the consultation and increase the expenditure needed to complete the consultation project.

ICT

The growth in Information and Communication Technology has meant that it is now being actively used by organisations during consultations with the internet and online surveys in particular playing a larger role.

The advantages of using the internet are that it is inexpensive, allows stakeholders to respond quickly to a proposal and allows information to be easily updated. Regulatory bodies should include details of all consultations on their websites and allow participants to return responses electronically on draft documents. It must be borne in mind here that certain stakeholders and members of the public may have limited access to the internet, which may affect response rates if this method is over-relied on. It is recommended that all public sector bodies have a dedicated consultation section on their websites.[60]

Public Meetings

Public meetings are meetings at which any person can attend. They are used in consultations to provide a forum for a wide range of people to receive information and then give their views on a particular issue. When used in consultations however, public meetings will usually attract members of the public with a specific interest in the issue for consultation and are therefore unlikely to be representative of the general population.

Prior to the introduction of any new clinical guideline, the Scottish Intercollegiate Guideline Network (SIGN), a Scottish organisation which develops clinical guidelines in order to improve the quality of patient care, holds a national open meeting to discuss the draft recommendations of each guideline.

User Panels

A user panel consists of a group of users of a particular service who meet on a regular basis, usually with senior management from the organisation which is using the panel as a forum for consultation. The panel is used to discuss user concerns, give early warnings of problems and help organisations come up with ideas or solutions for difficulties that they are facing. If the organisation is considering implementing any changes to its activities, the panel is a particularly useful means of receiving service user views on such changes. User panels are relatively inexpensive to operate and help to create a continuing dialogue between an organisation and service users.

Citizens' Panels

Citizens' panels operate in a similar manner to user panels except that they are composed of a representative group of members of the public as opposed to service users. In addition, these panels are typically much larger than user panels. Similarly to user panels, citizens' panels are often used to gauge public opinion on a proposed change.The National Institute for Health and Clinical Excellent (NICE) is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health in England and Wales. It makes use of a 'Citizens Council' to inform its clinical guidance. The council consists of 30 members of the public, a third of whom are replaced annually, facilitated by an independent organisation. The Council can question witnesses and make non-binding recommendations. If NICE decides not to take on board the views of the Council, it must explain why its decision differs from that of the Council. An evaluation of the NICE Citizens Council undertaken in 2005 concluded that it has been an undoubted success.[61]

2(d) Identify the appropriate timeframe for the consultation.

It is important to allow a sufficient time period for consultation both in terms of the time allocated for participants to give responses and also the overall time required to complete all three stages of a consultation project. A common pitfall is to underestimate the time involved in consultations.[62] An appropriate timeframe must of course take account of the methods which have been chosen for the consultation.

In the formal consultation on the UK Department of Health's Draft Code of Practice on the Revised Mental Health Act 1983 stakeholders were given 12 weeks to submit written views with the intention of publishing the final revised code of practice nine to ten months later.[63] The European Commission uses a period of eight weeks in which to carry out consultations and the UK Cabinet Office's guidelines recommend that a minimum of 12 weeks should be allowed for a written consultation (2004).[64] Based on these guidelines, agencies should aim to allow between 8 and 12 weeks for stakeholders to respond to written consultations. Different time periods may apply where other methods are used for the consultation.

It is clearly essential that consultation dates are not set too close to key deadlines in overall policy development. Sufficient time should always be set aside to collate and analyse feedback from consultations and to implement any necessary changes. Consultation can for instance indicate opposition to a particular proposal which may lead to delays in developing final proposals.[65]

2(e) Decide if pre-consultation will form any part of the project.
Pre-consultation occurs when an organisation decides to employ consultation methods to elicit views from some stakeholders prior to the commencement of the formal consultation phase. All of the tools used in pre-consultations will often take place in the standard consultation practices of organisations so it is important to ask if the eliciting of feedback at an earlier stage will bring any added benefit to the process. Obtaining the views of key informants on a draft set of standards before the commencement of formal consultation might be useful where a number of implementation difficulties with some of the standards have been foreseen for instance.

Before the start of its formal consultation on the Draft Code of Practice on the Revised Mental Health Act 1983, the UK Department of Health carried out a number of pre- consultation exercises. Prior to the development of the Draft Code, an Illustrative Code was produced. A number of workshops for relevant stakeholders were organised in different locations in the UK.

Further workshops were held which looked at specific sections of the illustrative Code. In addition, as the Mental Health Bill passed through parliament, revisions were made based on comments from members of parliament and other stakeholders. All of these influenced the final development of the draft Code.[66]

2(f) Identify how prepared and able the organisation is itself to carry out the consultation.
All consultations should be costed and time-bound in advance of taking place. An assessment of the resources available in the organisation will determine the degree to which staff are involved in managing and carrying out any given consultation. Where resource issues suggest that the organisation would be unable to undertake the consultation itself, it should consider using external consultants to carry out the work. The budget available for a particular consultation will also influence the manner in which a consultation is carried out including the methods chosen for the consultation. For example, face-to-face in-depth interviews are more expensive to carry out than structured interviews conducted by telephone.

B   EXECUTION

The following actions should be taken in the execution of a consultation.

- **Publicising the consultation.**
  It is important that stakeholders and members of the public are aware that the consultation process is taking place should they wish to express their views on the matter being consulted. This also demonstrates a commitment to listening to the views of interested parties.

  At a minimum, the stakeholders that have been identified in the planning stage should be informed in writing or by email of all the relevant details of the consultation. In addition, a dedicated consultation section on the organisation's website is recommended.

  Consideration should also be given to using the following methods, while bearing in mind the allocated expenditure for the consultation:
  - Advertising in national or regional newspapers or local radio; and
  - Advertising in sector publications or the newsletters of representative organisations.

  Staff of an agency undertaking an external consultation exercise should also be informed when such an exercise is taking place and provided with a point of contact in the organisation who is overseeing the project to address any consultation queries.

- **Including appropriate and accessible materials in the consultation exercise.**
  Appropriate and accessible materials should be circulated upon commencement of a consultation exercise. The material required will depend on the methods being employed and the stakeholders being consulted. Written consultations are more likely to involve the preparation of more material than other methods such as focus groups. However, appropriate information should always be circulated in advance of any form of consultation. The following considerations are particularly relevant to written consultations but can be adapted to suit other methods. They will ensure that consultation information is appropriate and accessible to as wide range an audience as possible:[67]
  1 Prepare a consultation document for each consultation exercise;
  2 Include in the consultation document a brief background to the subject of the consultation exercise (code of practice, regulations, etc.) and communicate the purpose and objectives of the consultation exercise to stakeholders in advance of obtaining feedback. This is important so that participants have realistic expectations of what to expect from a particular consultation;
  3 Highlight the questions that are being asked in the consultation document;
  4 Include details of how submissions can be made and the name, address, telephone number and e-mail address of a person who respondents can contact if they have further queries;

5   Indicate a deadline for responses, and wherever possible an outline of the proposed timetable for the rest of the decision-making and implementation processes;

6   Use language that is simple and accessible, avoiding the use of jargon or technical language, unless intended for a specific audience. Where technical advice is unavoidable, make sure that its meaning is clarified;

7   Do not assume that people will be familiar with the way statutory agencies work. Structures and processes should be explained wherever possible;

8   Include a request that those responding should explain who they are and, where relevant, who they represent;

9   Include a list of the organisations being consulted. Agencies should also ask participants to advise them of any other organisations/individuals who should be consulted;

10 Include a statement that responses will normally be published unless they are confidential subject to the provisions of the Data Protection Acts 1988 and 2003 and the Freedom of Information Acts 1997 and 2003;

11 Consider making the consultation document available in a variety of formats, such as an easy-to-read version which would be appropriate where an important stakeholder group included persons with an intellectual disability. Formatting and layout should also have people with visual impairments in mind - consider the size of font, arrangement of text on the page, minimal use of underlining and of colour contrast. What works in print does not always transfer well to a website; and

12 Acknowledge receipt of all written submissions received.

C   ANALYSIS AND EVALUATION

The final stage in the consultation process involves the analysis of feedback and an evaluation of the whole consultation exercise.

- **Analysing and reporting back on the responses/feedback received**
  Once the formal consultation phase ends, the feedback should be collated and analysed. The optimum means of analysing the data will largely depend on which methods were used to obtain feedback from participants. A written consultation will often require responses to a series of questions or comments on specific sections of a document, which generates a large amount of qualitative data. A thematic analysis of responses to a consultation will usually be the most useful way of presenting the results in a consultation report.

Thematic Analysis
This involves presenting data by feedback on key consultation themes. A thematic analysis was for example used by the Canadian Ministry for Children and Families in the analysis of responses it received to its consultation questions on the 2003 *Child and Youth Mental Health Plan*. The report's analysis categorised much of the data by the priorities that different groups of stakeholders assigned to proposals. This enabled it to present commonalities between the views of different stakeholders and to present a quantitative analysis of the priorities of alternative groups.[68]

It is recognised as good practice to publish a final consultation report or "Statement of Outcomes" to ensure openness and transparency in the process.[69] This report should summarise key themes from the submissions received and outline the actions that will be taken by the organisation as a result. The consultation findings may also be communicated by means of information/briefing sessions.

The UK Department of Health recently published a report on the consultation exercise on the draft revised Code of Practice on the 1983 Mental Health Act. After summarising the responses to individual sections of the code, a paragraph outlining the government's reasons for declining or approving suggested changes was included. In most cases where the government approved of the recommended changes, chapters of the Code were rewritten to take account of this.

Privacy, Confidentiality and Anonymity
It is especially important to consider issues of privacy, confidentiality and anonymity when publishing the findings of a consultation. Therefore, the consultation document should clearly inform stakeholders of the intention to publish findings. Consultation feedback cannot generally be held on a confidential basis. However, organisations should not include personally identifying information in a consultation report.

- **Reviewing and evaluating the consultation.**
  A review and evaluation of the consultation exercise is vital to properly establish if the consultation was effective i.e. if it met the broad aims that were set out in the planning phase of the project. The UK Cabinet Office's guidelines recommend that if possible, an evaluation should also be carried out during the consultation process i.e. it should be considered in all three phases of the project. This allows problems to be identified and addressed as they arise.

  For instance, if during the consultation period, it becomes apparent that some of the consultation aims are not being met, such as obtaining adequate feedback from a pivotal interested party, then the reasons for this could be examined at the time and solutions

explored with stakeholders. It may be possible to implement these solutions during the formal consultation period. Identifying if a further phase of consultation is required also inevitably involves some review of the project.

Any consultation review should attempt to answer all of the following questions:

- Did the consultation achieve its objectives?
- Did the consultation reach its target audience? Was this audience representative?
- Did the consultation provide all participants with an equal opportunity to take part?
- Were the methods appropriate to the objectives?
- How much time and resources, human and financial, were actually used in comparison to what was anticipated? Was the consultation cost-effective?
- Was the process transparent and easily understood by those participating?
- Was the consultation timetable maintained? If not, why not?
- What was learned from running the consultation and what can be improved in future consultations? How can this learning be shared with colleagues?[70]

SUMMARY OF KEY CONSULTATION ACTIONS

1 **Build consultation into the organisation's regular planning cycle and consult early in the development process.**

2 **Develop a consultation plan for each consultation process. The following should be addressed in the plan.**

   2(a)   **Define the subject, purpose and objectives of the consultation exercise.**

   2(b)   **Identify the stakeholders who should be consulted.**

   2(c)   **Identify the appropriate methods to achieve the objectives of the consultation and to reach the stakeholders who have been identified.**

   2(d)   **Identify the appropriate timeframe for the consultation.**

   2(e)   **Decide if pre-consultation will form any part of the project.**

   2(f)   **Identify how prepared and able the organisation is to carry out the consultation itself.**

3 **Publicise the consultation.**

4 **Include appropriate and accessible materials in the consultation exercise.**

5 **Analyse and report back on the responses/feedback received.**

6 **Review and evaluate the consultation.**

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Appendix 2: Consultation Plan Template

Consultation Name	34
Purpose and Objectives of the Consultation	
Consultation Participants	
Proposed Methods for Consultation	
Timeframe for Consultation	
Resources Required/Necessary Resources in Place on the Organisation to Carry Out Consultation	
Potential Risks	
Strategies to Maximise Participation of Relevant Stakeholders	
Where to Publicise *Internal and External*	
Information to be Provided to Stakeholders on Consultation	
Analysis and Feedback	
Evaluation	

Appendix 3: Evaluation Form - ISQSH & HCI (2009)

STAGE ONE: Assessment of Current Level of Public and Patient Involvement					
1.0 Plan	Disagree Strongly	Disagree	Neither	Agree	Agree Strongly
Q1.1 There is an identified need for increased public and patient involvement in my organisation.	1	2	3	4	5
Q1.2 There is a specific planning process for public and patient involvement in my organisation.	1	2	3	4	5
Q1.3 There are defined objectives regarding public and patient involvement in my organisation.	1	2	3	4	5
Q1.4 Stakeholders are consulted when objectives are being defined.	1	2	3	4	5

2.0 Do	Disagree Strongly	Disagree	Neither	Agree	Agree Strongly
Q2.1 Public and patient involvement has been specifically incorporated into my organisation's vision, mission and values.	1	2	3	4	5
Q2.2 Public and patient involvement has been utilised in the development of my organisation's strategic plan.	1	2	3	4	5
Q2.3 There is a defined strategy for maximising public and patient involvement in the delivery of the organisation's services.	1	2	3	4	5
Q2.4 There are clearly defined communication channels to disseminate information regarding public and patient involvement.	1	2	3	4	5
Q2.5 Activities are being conducted to promote a public and patient involvement culture.	1	2	3	4	5

2.0 Do (cont.)	Disagree Strongly	Disagree	Neither	Agree	Agree Strongly
Q2.6 The management and governance of the organisation are supportive of the public and patient involvement process.	1	2	3	4	5
Q2.7 There are specifically designated staff with responsibility for promotion of public and patient involvement.	1	2	3	4	5
Q2.8 Staff have received training and education regarding participation in public and patient involvement.	1	2	3	4	5

Q2.9

What public and patient involvement activities are currently in use in your organisation? (tick each activity currently in use):

- ☐ Information Booklets - Organisational General
- ☐ Information Booklets - Care Specific
- ☐ Telephone Helpline
- ☐ Staff Communication - Education
- ☐ Website Information
- ☐ Patient Videos - Organisational General
- ☐ Patient Videos - Care Specific
- ☐ Audio Information - CD/Tapes
- ☐ In-House Education
- ☐ Surveys - Organisational General
- ☐ Surveys - Care Specific
- ☐ Complaints System
- ☐ Feedback System
- ☐ Comment Cards
- ☐ Patient Charter
- ☐ Focus Groups
- ☐ In-depth One-to-one Interviews
- ☐ Patient Councils
- ☐ Patient Representation (Care Groups)
- ☐ Patient Representation (Service Planning)
- ☐ Advocacy Officer
- ☐ Community Meetings
- ☐ Health Promotion Campaigns
- ☐ Defined Involvement in Care Plans
- ☐ Other (Please Specify)

Total number of activities circled:

3.0 Check & Act

Q3.1
What public and patient involvement activities (in your organisation or elsewher) seem to be the most beneficial?

_____
_____
_____
_____
_____
_____
_____
_____

Q3.2
Of the public and patient involvement activities currently being conducted by your organisation, how many have undergone evaluation?
(please give details)

_____
_____
_____
_____
_____
_____
_____
_____

Total number of public and patient involvement activities which have undergone evaluation: _____

Q3.3
Have any improvements arisen and been implemented as a result of evaluation of the public and patient involvement activities? (please give details)

_____
_____
_____
_____
_____
_____
_____

Total number of improvements implemented as a result of evaluation: _____

Total Numerical Score for Stage One Quantitative Analysis:

STAGE TWO:
Reflection and Opportunities for Improvement

Q4.0

Summarise your organisation's areas of excellence in public and patient involvement activities.

Q5.0

Outline any opportunities for improvement in the area of public an patient involvement for your organisation.

Q6.0

Outline any existing plans (including determined timeframes and responsibilities) proposed to address these opportunities for improvement.

Q7.0

What public and patient involvement activities do you hope to see implemented in the next two years.

HEALTH & SOCIAL CARE
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