# Strengthening Midwifery Toolkit

# Module 2

## Legislation and regulation of midwifery - making safe motherhood possible

World Health Organization

**WHO Library Cataloguing-in-Publication Data**

Strengthening midwifery toolkit.

Contents: Modules: 1. Strengthening midwifery services: background paper - 2.Legislation and regulation of midwifery: making safe motherhood possible - 3.Developing standards to improve midwifery practice - 4.Competencies for midwifery practice - 5.Developing a midwifery curriculum for safe motherhood: guidelines for midwifery education programmes - 6.Developing effective programmes for preparing midwife teachers - 7.Supervision of midwives - 8.Monitoring and assessment of continued competency for midwifery practice - 9.Developing midwifery capacity for the promotion of maternal and newborn health - Annex 1: a model curriculum for midwifery education and practice.

1.Midwifery - standards. 2.Midwifery - education. 3.Midwifery - legislation and jurisprudence. 4.Maternal welfare. 5.Obstetric labor complications - prevention and control. 6.Reproductive medicine. I.World Health Organization.

ISBN 978 92 4 150196 5 (NLM classification: WQ 160)

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# 1. Introduction

The aim of this module is to outline the ways in which legislation and professional regulation of midwives can be employed to enhance national and international efforts to reduce maternal and newborn morbidity and mortality and improve reproductive health. The evidence from numerous studies conducted in diverse global settings that explored the direct and indirect causes of maternal morbidity and mortality (maternal audit studies) shows clearly that the vast majority of deaths related to pregnancy and childbirth are avoidable, but require a skilled person to be able to provide quality care, which must include being allowed to perform certain life-saving interventions (Pattinson et al., 2003; Fawcus SR, van Coeverden de Groot HA, Isaacs S; 2005; Dumont, Tourigny & Fournier, 2009; Okong et al., 2006; Kongnyuy, Leigh &van den Broek, 2008; Dumont et al., 2009; Qiu et al., 2010). This module of the World Health Organization *The Strengthening Midwifery Toolkit* addresses a range of issues related to the statutory or regulatory (legal) authority that governs the practice of midwifery in any country and the authorization of individuals to engage in midwifery practice (occupational or professional registration and/or licensing).

While the emphasis in this paper is on legislation to support midwifery practice, legislation also has to be considered for other health care workers who function in the reproductive health field, particularly those who provide pregnancy and childbirth care. Similarly, reproductive health legislation has to be considered in relation to other laws that influence the position of women in society generally (Cook, 1998; Andorno, 2009; Garcia-Moreno & Stöckl, 2009).

## 1.1 The challenge

The contrast between maternal mortality reduction in the industrialised world and in many developing countries highlights the challenge facing those countries where the level of maternal deaths is unacceptable. It seems logical first to identify the desired outcome and, secondly, to identify the barriers to achieving that outcome, before finally considering legislative approaches to bring about change and to support good practice.

Millennium Development Goals were endorsed by 189 countries, as a commitment to global development, security and human rights (UN, 2000). Goal #4 *"reduce child mortality"* and goal #5 "*to improve maternal health*" are clearly linked to the quality of health care services received by pregnant women and their newborns, as offered by their providers and at the service delivery site. Nevertheless, maternal and newborn morbidity and mortality rates are influenced by a wide range of issues, many of which lie outside the health sector. They include the available resources (both human and financial), the current economic and nutritional status of the population, the degree of political stability of the country, as well as political commitment to maternal and newborn health, the position of women in society, the level of female literacy and many others (Moss, 2002; UNFPA, 2005; WHO, 2005; UNICEF, 2006).

These factors contribute substantially to the wide variation in the risk of any woman dying as a result of pregnancy or childbirth during her lifetime, which was estimated to range from about one in six in the poorest parts of the world compared with about one in 30,000 in Northern Europe (Ronsmans & Graham, 2006), and concentrated in sub-Saharan Africa and Asia (Hill et al., 2007). They also contribute to the deaths of over 7 million babies during pregnancy or the

newborn period (WHO, 2005), although recent estimates indicate an accelerating rate of decline (Rajaratnam et al., 2010; WHO 2010). The authors of a recent comprehensive review of *"what works in reducing maternal mortality*" conclude that access to skilled attendance at births would be a key strategy (Campbell & Graham, 2006). These sentiments are echoed by the authors of a more recent review of the evidence-based interventions that have proven effective in reduction of intrapartum-related stillbirths and neonatal deaths (Lawn et al., 2009). Authors of both reviews noted that on a global scale, all too often the political will to take effective action is lacking.

Maternal mortality is a symptom of the underlying neglect of women's health and well-being. Deaths during pregnancy and childbirth are almost entirely avoidable with existing skills and technologies, yet services to provide appropriate maternal health care and safe obstetric interventions are not universally available. All women should have access to high quality prenatal, delivery and postpartum care in the context of primary health care, including access to referral services for obstetric complications.

*Source: WHO,1995*

### 1.2 A contribution to resolution

A workforce of midwives with a common body of knowledge and skills (Module 4) could have a measurable impact on maternal morbidity and mortality in any country. Matching this knowledge and these skills to the specific major causes of maternal deaths (haemorrhage, sepsis, obstructed labour, eclampsia and abortion) could result in a significant reduction in deaths from these causes (Ronsmans & Graham, 2006). However, this will only work with the necessary legislative framework in place which provides for a skilled midwifery workforce supported by an effective system of regulation**.** This view does not stem from a narrow view of professional protectionism, but from historical evidence and the fact that the midwife's role spans that period of a woman's life, which involves a number of major risks to her health and life (Louden, 1992). To be "with woman" (the literal translation of the word "midwife" in English) in the 21st century must include being with her as the expert in normal birth as well as in whatever circumstances she experiences pregnancy and childbirth, particularly when life-threatening complications of pregnancy arise.

Furthermore, an enabling legislative framework for promoting and enhancing reproductive health and rights is crucial for achieving the goals of safe motherhood and saving newborn lives (Freedman, 2001; Cook & Dickens, 2002; WHO, 2003; Germain, 2004; Fathalla, 2006; Milliez, 2009). Such a framework also enables the midwife to positively exploit the potential which her [1] role offers to bring about major improvements in maternal and newborn morbidity and mortality rates through improved quality of provision of maternal and newborn health care services (Thompson, 2004).

## 2. The value and purpose of midwifery legislation and regulation

A human rights-based approach to reduction of maternal mortality provides a legal or development-centred framework or both for strengthening policy and programme interventions.

*Source: Manandhar, Osrin & Shrestha, 2004*

[1] The use of the female gender reflects that in many countries midwifery is seen as exclusively open to women. However in a number of countries men now enter into this profession. The international definition has been updated to reflect a more gender-neutral language; however, this guidance uses the female gender for ease of use.

Professional regulation of midwives should represent a partnership between the public which expects it, the individuals who practice it and the boards or committees who administer the system (Norman, 2000). There is now strong evidence that underpins the recent recommendation that all women should have a skilled attendant during pregnancy, childbirth and the immediate postnatal period, in order to advance the goal of making pregnancy safer (WHO, 2004). Information about the knowledge, skills and abilities (KSAs) required of the skilled attendant is also clear (See Module 4 of this *Toolkit*), and clearly linked to the evidence that demonstrates the relationship between high quality and timely application of these KSAs and the quality of the outcomes of maternal and newborn care. If the full potential of midwives as skilled attendants is to be realized, they need to practice within a supportive (positive) practice environment that enables them to use their best critical thinking skills and clinical judgement to make appropriate assessments, select appropriate interventions, including life-saving skills, and use them accordingly. Supportive legislation[2] is a critical component of that enabling environment.

Whether the need is to develop new legislation, or amend legislation that presently exists, it is a fundamental fact that appropriate legislation is part of the essential foundation for the effective development of health services. For example, in low-resource settings, in order to meet community healthcare need, midwives may be placed in the situation of needing to prescribe or dispense drugs, or perform certain functions, even in the absence of supervision, legislation and regulation (Miles, Seitio & McGilvray, 2006); a clearly undesirable situation from the perspectives of the individual, the community and the public good.

The public purpose of midwifery regulation therefore (Spoel & James, 2006) includes:

- protection of the public from unsafe practices;
- promoting quality of services (through standards of practice, competencies and evaluation of outcomes);
- informing the public of what services to expect so they can make choices;
- fostering the development of the profession;
- conferring accountability, identity (including protection of title), and status upon the professional practitioners;
- promoting socio-economic welfare of the practitioners.

## 2.1 Developing new regulations

This enabling legislation may need to be newly developed in some countries. WHO (2002) and the ICM (2010) have provided guidance for this effort. The steps needed to develop new legislation require that midwives engage many other interested and affected stakeholders, including women, in a coalition of support, first to raise awareness of the need and value of such legislation, and then to take action to develop appropriate legislative guidelines, enact this legislation through regulation, and monitor its implementation. The action steps can be broadly outlined as follows:

- raise political awareness of the need for legislation that regulates the profession, and engage political action and support to pursue it;
- become knowledgeable about the legislative and governmental processes that would be essential to the regulatory development process;
- set goals and develop a plan of action (including identifying responsibilities and setting a timeline);

[2] Legislative and regulatory terminology varies greatly by country.

- establish a position on midwifery issues, especially the purpose and goal of midwifery, principles and philosophy of midwifery care;
- establish a desirable and preferred model of midwifery regulation (e.g. as an autonomous profession, distinct from nursing, or another model);
- gather data to support the identified goals and position;
- involve all relevant stakeholders in an action plan for development and implementation of midwifery regulations;
- form coalitions that will advocate for the process and pursue the steps cited in the action plan. Coalition members can include other relevant health care professions, women's groups, and others (both national and international) concerned with maternal and newborn health, social development and mobilisation, and poverty alleviation;
- provide feedback to all stakeholders, throughout the process. It is important to ensure that all who may be affected by the new regulation and licensing rules and mechanisms are kept fully informed of progress and have the opportunity to offer their feedback.

### 2.2 Adapting current regulations

In other countries, the legislation authorising the practice of midwifery is in place but there are constraints that limit the realization of the midwives' full potential, leading to the need to reform current regulatory guidelines (Fealy et al., 2009). For example, in a number of countries the legislative framework exists to enable midwives to work as autonomous practitioners providing a whole range of midwifery services from preconception to the end of the postnatal period (Reed and Roberts, 2000). In other countries the midwife may be required to work under supervision or guidance of physicians.

The scope of practice may also be defined differently within practice authorisations, and these practice restrictions may impede realisation of the full scope of midwifery practice.
For example there may be prohibitions on the performance of certain functions, or they may be authorised only for midwives who have achieved a certain level of education (Larsen, 2004; de Bijl, 2005). For example, there may be broad restrictions on the midwives' authority to select, or dispense certain drugs (Geyer, 2001; Adekunle et al., 2001; MacEachern, 2003; Adame & Carpenter, 2009). In some circumstances, these practice restrictions can impede the delivery of safe or even life-saving care (e.g. antibiotics for treatment of infection; uterotonics for control of haemorrhage). Other examples of functions that are often restricted include performance and repair of an episiotomy or perineal repair, or manual vacuum aspiration in the event of incomplete abortion (Foster et al., 2006; Berer, 2009; Akiode et al., 2010), which can result in the need for urgent transfer to another birth site or facility for further care.

## 3. Establishing a regulatory authority for midwives: models and strategies

The main functions of a professional regulatory system are to bring order and control to a profession and to protect the public by:

- setting standards for entry to the occupation or profession
- ensuring, as much as possible, the maintenance of standards
- providing a mechanism for dealing with professional misconduct
- maintaining an effective public register of all those eligible to practice.

There are several options for establishing the regulatory authority for midwifery practice in any country. Each has advantages and disadvantages, depending on the status of the profession, and the political, social and cultural environment in the country. Two common mechanisms are offered in detail.

- A statute (or law) could be passed by the country-level authority that regulates midwifery practice, and defines its scope. The statute would establish a regulatory body to implement the provisions of this statute. Advantages of this approach include visibility of the midwifery workforce, and acknowledgement of its role within the country's health care system. This provides a certain status for the occupation/profession and offers it some protection, including that of protection of title. Disadvantages include the fact that changing the statute (law) is a lengthy and difficult process. The specific details contained within the statute (law) could become outdated over time, as new evidence emerges.

- A statute (or law) could be written that establishes midwifery as a specific and recognized occupation or profession, but that delegates the authority for establishing standards and guidelines to another regulatory body. The distinct advantage of this approach is the flexibility that this body has to act more quickly to update these standards and guidelines, when indicated. A second advantage is that the membership of these regulatory boards can (and should) include representatives of the midwifery cadre that is being regulated, and representatives of the consumer public. Disadvantages of this design include the potential for unbalanced representation, such that members of the midwifery cadre are a minority of those who actually implement standards of practice for the profession.

An enabling regulatory mechanism must be flexible and pragmatic and yet at the same time must provide a framework for good governance of the profession. It is generally believed that the most effective regulatory mechanisms are those that are understood and valued by society and the professional group. It is essential that midwives take the lead in reviewing proposed legislation and regulations for the occupation/profession, and in considering new approaches, as they are the individuals who can best interpret the occupation/profession and its values to others. The International Confederation of Midwives can provide resources (e.g. the list of *Essential Competencies for Midwifery Practice*, and the *Global Standards for Midwifery Regulation)* that can be adopted, or referenced, for use in regulatory language at the country level.

Accountability of the profession to civil society is also crucial. Effective regulation is dependant on civil recognition, confidence in the mechanism and system in place and the ways in which these are made operational in the country. A checklist for monitoring the process of establishing a new regulatory framework is offered as an annex to this module.

**A GLOSSARY OF MIDWIFERY REGULATORY TERMS**

***Certification:*** A process and procedure of external assessment or examination by which an individual is determined to possess a minimally acceptable body of knowledge and/or skills. Certification may be voluntary or mandatory, as a condition of licensure.

***Guideline:*** A recommendation for a way of acting

***Licensure (n) / license (v):*** The process and procedure by which an individual is granted authority to enter into practice; the document that acknowledges that authority.

***Malpractice***: lack of knowledge or experience, or the negligent performance of duties that result in patient injury.

***Professional misconduct:*** Work-related behaviours which are unworthy or unethical.

***Registration (n) /register (v):*** The process and procedure by which an individual is acknowledged as having authority to practice; the official roll of individuals who have been registered. [Note that this term is used as an alternative to licensure in some country jurisdictions.]

***Regulation:*** Prescriptive guidance for the enactment of the provisions of statute (law), whether defined within the statute or developed by another institutional body (e.g. institutional ministry) that has the authority to implement, interpret or make the statute specific; an authoritative rule (e.g. ministerial decree, order, regulation) dealing with details or procedure

***Standard***: An agreed manner of performance; a benchmark for expected performance (e.g. as established by consensus committees or professional associations) (also known as a "rule" of practice)

***Statute (Law):*** A decree enacted by the highest legislative assembly in the jurisdiction (e.g. Parliament, Congress, National Assembly, State Governments or Rulers Court)

# 4. Regulations, rules and guidelines for the practice of midwifery

The professional regulatory body has the authority to enact the rules and guidelines for the practice of midwifery in the country. The component elements of these rules and guidelines are depicted in Figure 1, some of which are further elaborated in the sections that follow.

## 4.1 The constitution and composition of the regulatory body

Many countries have established a single regulatory body that governs a number of occupations and professions that share components of a scope of practice, as, for example, the Nursing and Midwifery Councils of the United Kingdom and the countries of Malawi and Ghana. Other countries have established regulatory bodies that specifically address midwifery as an autonomous profession (e.g. the New Zealand Midwifery Council). There are variations, of course, depending on the manner in which countries have delegated jurisdiction over matters such as licensure to states or provinces. For example, the practice of midwifery is authorized in some provinces of Canada and not in others; regulatory authority is retained at the provincial level. The practice of midwifery is regulated by individual states within Australia (Brodie & Barclay, 2001) and the United States. The majority of the U.S. states require that midwives also be nurses, but even in the states that have this requirement, the regulatory functions may be delegated to a nursing board, joint professional boards (e.g. medicine or public health), or to a separate midwifery board or council (Reed & Roberts, 2000).

The direct involvement of midwives in the work of this regulatory body (including elected or appointed membership on the regulatory board) will have a direct effect

on the development of regulations, rules, standards or guidelines that will create an enabling framework for professional practice (James & Willis, 2001). Midwives are best able to define their own practice, and the most knowledgeable about the circumstances that serve as barriers or restrictions to quality service delivery. Participation of midwives on these boards will help to ensure that these regulations are written in the broadest (least restrictive) sense, to enable the midwife to practice to the fullest extent of her competency, and also enabled to use her professional best judgement under challenging circumstances.

It is also critical to involve the midwifery member association in the country in shaping the design of the regulatory system, through both consultation and advocacy. The association may be the best source of information and evidence about issues that are particularly specific to midwives, such as a code of ethics, and the essential practice competencies. These do not have to be newly developed, but can be adopted or adapted from the materials that have been developed and promulgated by others, such as the International Confederation of Midwives and the WHO. Countries can only benefit by the wisdom acquired through the experience of their peers in other international settings (Jowett et al., 2000; Carty, 2005).

Finally, in order to ensure that regulations and licensing systems, especially the standards set for midwifery practice, have legitimacy, they must be developed through a participatory process with the involvement of other stakeholders. Key stakeholders include members of the public, in particular those representing the views and rights of women. Having women's health activists involved in the drafting of policies, laws and regulations, and in the actual regulation of midwives and midwifery practice will ensure that a woman, her newborn and family will be the focus taken in these areas.

Membership of a midwifery regulatory body therefore should ideally include:

- maternal and newborn health policy makers at national level;
- representative(s) of the Government;
- midwife educators;
- practitioner(s) in current clinical practice;
- representatives of the professional membership association(s) of midwives, to represent the occupational and welfare concerns of practitioners, as well as professional issues;
- member(s) of the general public representing women's interests;
- women (including beneficiaries of midwifery services);
- lawyers or others qualified in the drafting of regulatory language;
- representatives from relevant allied professions.

In many countries there is a mix of elected and appointed members who make up a regulatory body. The system for election or appointment onto the regulatory body should be transparent. The interest of upholding the public good and the needs of women and their newborn and families, fairness, and equity should be paramount in deciding on the composition and constitution of such a body.

## 4.2 Guidelines for midwifery education programs

Midwifery regulation should be developed to ensure minimum professional standards of midwifery education and practice (Brodie & Barclay, 2001). The guidelines that are established for the length of programmes of study, and the core competencies to be taught in those programmes are commonly defined by the authoritative bodies that regulate the practice of the profession.. The delegation of this responsibility to a regulatory body helps to define the common standard expected as the outcome of all programme graduates who will use the title "midwife" in the country, so that other health professionals and the public can have a reasonable understanding and expectation of the scope of practice. This authoritative body can also address ways and means of reviewing the quality of education programmes, through the provision of oversight and peer review (accreditation) of teaching institutions (Forrester, 2009).

A model curriculum of midwifery studies is provided as an annex to this *Toolkit*. This model curriculum can serve as a resource that can be incorporated (adopted) or adapted to meet the specific needs of the country situation. The model curriculum outlines the essentials for education of a community-focused midwife, who, because of her environment, will also require preparation to provide effective care for women who are undergoing normal pregnancy and childbirth, but also for women and newborns who experience complications, many of which are life-threatening (i.e. life-saving skills).

There may be different levels of qualification for various cadres of midwives in a single country, such as auxiliary nurse-midwife or direct entry [non-nursing] midwife. The regulatory body may have authority to define the educational patterns and the expected outcomes of the various educational pathways. Other countries may choose to establish separate regulatory boards for the various cadres, to ensure that there is sufficient representation of the particular cadre type on the board (or country equivalent) that has the authority to regulate practice.

## 4.3 Entry into practice and initial licensure

A primary purpose of licensing bodies is to protect the public from unsafe practice. Therefore, the expected outcomes of midwifery education programmes (the knowledge, skills and behaviours expected of safe beginning practitioners) are also often explicitly cited as the component elements of entry-into-practice requirements that are established by regulatory boards. There may be additional requirements, such as standardized testing (e.g. national certification or licensure examinations) as a requirement for first licensure. The regulatory body should also address equivalents for internationally qualified midwives; establishing mechanisms and pathways for reviewing their credentials, verifying qualifications, and determining the individual's fitness for practice under the requirements of the new (the receiving) country (Mead, 2003; Kingma, 2006; Bieski, 2007).

Regulatory boards are also the gatekeepers of the professional register of qualified midwives, i.e. the list of those who have complied with all statutory requirements for initial entry into practice, and for re-licensure. This information should be accessible to those seeking to employ midwives. A register is also very useful in workforce planning.

## 4.4 Requirements for assessment of continued competency

The authority to enter into practice may be given for the occupational/professional lifetime, or it may be time limited. Countries may develop regulations that require a reapplication from time-to-time for the authority to practice. These regulations may require evidence that the individual has engaged in a program of continuing education (for enhancement of knowledge) and/or reassessment of practice skills. An assessment of continued competency would be particularly important for those wishing to return to the profession after an absence from the workforce, and should be addressed in the regulations.

Maintaining current competency may be particularly challenging for midwives in countries where there is no regular program for the continuing educational development for midwives. To maintain standards the midwife needs adequate opportunities for practice in order to:

- sustain competence and confidence in the conduct of necessary clinical skills, particularly those for which the need does not often arise, but which are life-saving when needed (e.g. resuscitation of the adult or newborn);
- update knowledge and learn new skills, as the evidence that underpins practice is continually evolving;
- reflect on clinical practice regularly and learn from her experience; and
- understand and practice accountability, to her clients, to her managers/ employer, and to the general public.

Strategies for these assessments are discussed in Modules 7 and 8 of this *Toolkit*, which discuss basic and continued competencies for practicing midwives. The consideration of the importance of the continued competency of teachers in basic midwifery education programs is addressed in Module 6. These strategies could be referenced in the regulations as one approach for meeting any continued competency requirement that may be established in the regulations.

## 4.5 Standards of practice

The regulatory guidelines should incorporate reference to standards of high-quality practice. However, it is neither necessary nor efficient for the regulatory board to establish these standards, because the evidence that underpins clinical practice is ever evolving. Best practice standards change rapidly. Practitioners should be able to incorporate new recommendations for practice, and not be constrained in their practice by the need to await the updating of regulatory language. Regulatory boards can make reference to the existence of standards of practice issued from time-to-time by international or national authorities, and by midwifery membership associations. The WHO *Standards for Maternal and Newborn Care* are a single example of the many evidence-based practice guideline documents that can serve this purpose.

For the individual practitioner, an emphasis on personal professional accountability is perhaps the most important determinant of maintenance of standards. To assist practitioners, it is usual for the professional regulatory body to issue, from time-to-time, written guidance on important issues, such as record keeping (Dimond, 2005 a,b,c; Brous, 2009) and scope of practice requirements.

## 4.6 Professional misconduct

The primary legislation must enable the development of a mechanism for the discipline (e.g. warning or sanction) of practitioners or their removal from the professional register if they are found guilty of misconduct or malpractice. Misconduct might be simply defined as "conduct unworthy of a professional." What constitutes misconduct will differ among countries, but would likely include putting the profession into disrepute or several matters that are addressed in civil law (e.g. assault or theft from a client).

Malpractice might be defined as "lack of knowledge or experience, or the negligent performance of duties that result in patient injury" (Gündo mu ÜN, Özkara E, Mete S, 2004), i.e. the failure to provide acceptable levels of health care (Hugh & Dekker, 2009; Miola, 2009). Midwives have been reported to be responsible for several types of malpractice:

- wrongful disclosure of personal information about clients;
- incomplete monitoring of pregnancy and inaccurate assessment of pregnancy-

related conditions, leading to adverse changes in the client's health status (negligent care) (Mair, 1997);
- failure to detect pregnancy-related problems and to refer the woman to higher levels of care in a timely manner;
- failure to perform tasks in a skilful manner, resulting in injury to the client (e.g. inappropriate technique for management of breech delivery or shoulder dystocia) (Angelini & Greenwald, 2005);
- medication errors (e.g. route, region and technique of drug administration) (Jonsson, Nordén & Hanson, 2007).

In any circumstance, unprofessional conduct and professional misconduct can often be very difficult to detect, and even more difficult to "prove" with sufficient evidence to warrant a disciplinary action (Johnstone, 2004). The point of including reference to standards of practice (such as the WHO *Standards for Maternal and Neonatal Care)* (WHO, 2006) within a regulatory statute or guideline is to establish an objective, external, criterion of "best practice" to which the action(s) of any individual can be compared, and then considered in light of the particular practice circumstances (e.g. the site of care or the availability of alternative options). These standards will augment the expert witness testimony that will establish the expected standard of care under the circumstances.

It is important to note that an undesirable outcome is not necessarily the result of professional misconduct or unsafe practice. Some undesirable outcomes are unavoidable (such as congenital anomalies incompatible with life). Others occur despite the best efforts of midwives to intervene appropriately and to assist their clients to gain access to higher levels of care when circumstances warrant such action.

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**Figure 1:** Design elements of a midwifery regulatory system

**Components of a regulatory system for midwifery**

- Purpose of the regulatory system
- Structure of the regulatory body
- Specification for the composition and constitution of the regulatory/administrative body including
    - their powers
    - their functions
    - powers of the registrar
    - criteria for membership on this body (composition)
    - method by which members are appointed
    - terms of office of members
        - Length of each term
        - Number of terms that can be served without a break in service
    - officers of the body
    - reporting responsibilities
        - to whom they must report
        - how often reporting is required
        - the form of reporting required
- Definition of midwifery and of midwives
    - categories (cadres) of the professional that are governed by the regulations
    - responsibilities of each cadre
    - scope of practice of each cadre
- Requirements for entry into the profession
    - standards and guidelines for pre-service education programmes
    - competencies at entry into practice
- Mechanisms for initial licensing
    - testing requirements (if selected by the country), and minimum pass standard
    - equivalency licensing mechanisms for midwives educated in other countries
    - qualification verification
    - term of the initial license
    - initial license fees (if established by the country)
- Mechanisms for re-licensing and/or re-entry into the workforce
    - continued competency assessment requirements (if selected by the country)
        - updates for knowledge
        - reassessment of clinical skills
    - re-license fees (if established by the country)
- Standards of professional midwifery practice
- Protocol for dealing with misconduct and other unfit for practice issues
    - criteria for voluntary or involuntary removal from the registry
    - consequences for a finding of professional misconduct
    - appeal mechanism

**Optional components**

- Code of conduct/code of ethics or the general values and principles underpinning the professional practice of midwifery

# ANNEX: Achieving change in midwifery legislation and regulation for safe midwifery care

| Stage | Question | Yes | No | Action Required |
|---|---|---|---|---|
| **1. Establishing goals and principles** | Is the purpose of midwifery practice in the national context established? | | | |
| | Is there consensus on the categories of health provider(s) permitted to practice the art and science of midwifery in the national context? | | | |
| | Is the purpose for regulation and licensing of midwifery and those permitted to practice midwifery explicit and clear? | | | |
| | Is there a national definition (agreed by all stakeholders) of a midwife? Is the definition clear and sufficient to enable title protection? | | | |
| | Are the role and responsibilities of a midwife explicit and have they been agreed by all stakeholders? | | | |
| | Are the competencies required for safe midwifery practice explicit and do they ensure that the midwives providing midwifery care are able to fulfil their role and responsibilities as agreed nationally? | | | |
| | Do the competencies fit the ICM Essential Competencies for Basic Midwifery Practice and the WHO/ICM/FIGO list of competencies for a skilled attendant for pregnancy and childbirth? | | | |
| | Does the scope of practice for this practitioner meet the national priorities for safe midwifery care? | | | |
| **2. Legal constraints and barriers** | Do the national policies and laws related to drugs and medicines (including prescribing, administration and safety) permit the midwife to administer essential drugs to the women or newborn, including giving life saving drugs for management of a complication in pregnancy, childbirth and/or postnatal period? | | | |
| | Do the national polices and laws permit midwives (and others practicing midwifery), to carry out all the necessary care and interventions required to fulfil their role and responsibilities? | | | |
| | Do the national policies and laws permit midwives and others practicing midwifery to carry out all the necessary evidence-based life-saving procedures for safe pregnancy, childbirth and postnatal and neonatal care? | | | |

| Stage | Question | Yes | No | Action Required |
|---|---|---|---|---|
| **3. Strategies for developing effective legislation and regulation** | Is there a national task-force/committee or high-level forum established for revising and or drafting regulation and licensing for midwifery? | | | |
| | Does the national task-force/committee ensure representation from all stakeholders, including women, consumers and the general public? | | | |
| | Are there mechanisms to ensure that the voices of women as users or potential users of midwifery services are heard during development of the regulations? | | | |
| | Are there national evidence-based standards for midwifery practice and mechanisms for auditing and reviewing these standards? | | | |
| **4 Achieving the change** | Is there a process for national public consultation and consensus building on regulation and licensing governing midwifery practice, and is this widely known and time frames adequate to ensure all stakeholders can participate? | | | |
| | Are there clear timelines set and agreed for approval of new regulation and licensing for midwifery? | | | |
| | Are the roles and responsibilities of all stakeholders clear for achieving the revision/development of new midwifery regulation and licensing, including for implementation of the new regulations when finally approved? | | | |
| | Have all resources required for achieving the required change, including financial and human resources, been clearly identified? | | | |
| **5. Monitoring and evaluation** | Have clear indicators been established for monitoring implementation of the new regulations and licensing mechanisms? | | | |
| | Is it clear who is responsible for monitoring compliance with new regulations? | | | |


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ISBN 978 92 4 150196 5