Protection, promotion and support of breastfeeding in Europe: a blueprint for action

(revised 2008)



European Commission Directorate Public Health and Risk Assessment



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Unit for Health Services Research and International Health WHO Collaborating Centre for Maternal and Child Health







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Developed and written by participants of the project: Promotion of breastfeeding in Europe (EU Project Contract N. SPC 2002359)

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Abbreviations

BFH	Baby Friendly Hospital
BFHI	Baby Friendly Hospital Initiative
BFCI	Baby Friendly Community Initiative
CBSC	Communication for Behaviour and Social Change
CRC	UN Convention on the Rights of the Child
EU	European Union
EUNUTNET	European Network for Public Health Nutrition: Networking,
	Monitoring, Intervention and Training
EURODIET	Nutrition and Diet for Healthy Lifestyles in Europe
FAO	Food and Agriculture Organization
HIV	Human Immunodeficiency Virus
IBCLC	International Board Certified Lactation Consultant
IBLCE	International Board of Lactation Consultant Examiners
ILO	International Labour Organization
MDG	Millennium Development Goals
NGO	Non-Governmental Organization
UN	United Nations
UNICEF	United Nations Children's Fund
WBW	World Breastfeeding Week
WHA	World Health Assembly
WHO	World Health Organization
WHO/EURO	World Health Organization Regional Office for Europe

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Preamble

The Blueprint for Action^a was launched at the Conference on Promotion of Breastfeeding in Europe on 18 June 2004 in Dublin Castle, Ireland. Though based on a careful analysis of the situation, on a thorough review of effective interventions, on reports of successful national and local experiences, and on the consensus of hundreds of individuals and groups committed to protecting, promoting and supporting breastfeeding across Europe, the document was still the result of desk work. At the time the Blueprint was presented, nobody knew whether it would be a useful model and guide to national and local planning.

Hence the decision to apply for a second project that would field test the usefulness of the Blueprint. The project was approved and funded by the European Commission and took off in May 2005 in eight countries (or regions): Belgium, Denmark, France (Rhône-Alpes), Ireland, Italy (Tuscany), Latvia, Luxembourg and Poland (Lublin).

Some of these countries or regions had already a policy and plan for the protection, promotion and support of breastfeeding; some had to start from scratch. Some had implemented activities for years; some were lagging behind, as shown by deep differences in the estimated rates of initiation and duration of breastfeeding. All intended to develop or revise their policies and plans to hopefully increase the effectiveness of their interventions and improve breastfeeding rates and mothers' experiences of breastfeeding.

The implementation of the project met with difficulties of various nature and degree in different countries and regions, as described in the project report^b. Progress was accelerated in all participant sites, though not always at the desired pace and with the expected results. In all countries and regions, however, the Blueprint for Action proved to be a useful guide for the assessment of the situation and development or revision of policies and plans or, where this was not achieved, for the coordination of activities carried out at different levels of health and social services.

Based on the experience gained during the project, the Blueprint for Action was revised and updated. The contents of the original document were considered solid and the revised Blueprint is not substantially different from the previous one. The way the contents are organised, however, is different, to facilitate the use of the Blueprint as a planning tool by two groups of users:

- Policy and decision makers not necessarily versed in breastfeeding and involved in the development
 or revision of action plans, who are nevertheless influential for their kick off and progress and who
 need a brief exposure to the background and principles of the Blueprint.
- Professionals directly involved in the development or revision of action plans who need practical guidance at different steps of the planning process.

The changes in the sequence of sections and the parts that were modified or integrated with new text are:

- The original introduction referred to documents with which many planners were unfamiliar. These documents are now summarised in a number of annexes.
- A section on "What difficulties were identified in applying the Blueprint in the project sites" has been added.
- The overview of the current situation has been updated using the results of a survey with the same questionnaire applied in the previous project.
- Minor changes aimed at updating the information were made to the sections on determinants of breastfeeding and review of interventions.

a Download from http://ec.europa.eu/health/ph_projects/2002/promotion/fp_promotion_2002_frep_18_en.pdf

b Download from http://ec.europa.eu/health/ph_projects/2004/action3/action3_2004_18_en.print.htm

- Relevant and important documents on infant and young child feeding policies issued after 2004 have been integrated and referenced.
- The main text of the Blueprint starts with some hints on how to carry out an analysis of the situation. For this purpose, a tool used during the pilot project and derived from the original Blueprint was added in an annex.
- The section on policy, planning, management and financing includes paragraphs on developing a policy (with a sample policy in the annexes) and on issuing practice guidelines (with a reference to standard guidelines developed during the project).
- The section on planning is now followed by some indications on setting priorities and defining objectives. The section on management and financing has been expanded and completed with some hints on monitoring.
- The terms "Information, education, communication" have been replaced throughout the text by "Communication for behaviour and social change", thought to better describe the objectives and activities described under this heading.
- The sections on training, protection, promotion and support have remained substantially unchanged, with just some change in language and little updating.
- All the tables with recommended objectives, responsibilities, outputs and outcomes were moved after the text to facilitate reading this and to group all the tables for easier consultation.
- The section on monitoring has been updated and improved, and its tables were deleted; their content has been integrated into each specific table of activity.
- The list of authors and reviewers has been moved after the updated list of references, and a short glossary completes the Blueprint after the annexes.

The Blueprint for Action that readers will find in the following pages, therefore, is not substantially different from the original document, confirming the fact that this was based on sound knowledge, practice and experience. Hopefully this revision will make the Blueprint a more user-friendly tool for all those interested in improving the health and nutrition of infants and young children in Europe.

Note. Users of the electronic version of the Blueprint will be able to ctrl + click words underlined in blue to move quickly to the section of the document referred to by these underlined words.

Foreword to the 2004 edition

It is with great pleasure that I present this Blueprint for Action for the protection, promotion and support of breastfeeding in Europe, which has been developed by a project co-funded by the Directorate General for Health and Consumer Protection of the European Commission.

The promotion of breastfeeding is one of the most effective ways to improve the health of our children. It has also beneficial effects for mothers, families, the community, the health and social system, the environment, and the society in general.

There are numerous initiatives at local, regional, national and international level that promote breastfeeding. I believe, however, that the chances that these initiatives achieve good and permanent results will be much higher if action is based on sound plans including activities of proven effectiveness integrated into a coordinated programme.

The Blueprint for Action provides a framework for the development of such plans. The Blueprint will be made available to all those Governments, institutions and organizations who are willing to work together for the protection, promotion and support of breastfeeding. I invite them to use the Blueprint and translate its proposals and recommendations into action.

I am confident that these plans will contribute to meeting the demand of European citizens for better information for and support to the best start in life for their children.

I wish to thank the group of people who developed and wrote the Blueprint for Action for their contribution.



David Byrne Former European Commissioner for Health and Consumer Protection

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Executive summary

The protection, promotion and support of breastfeeding are a public health priority throughout Europe. Low rates and early cessation of breastfeeding have important adverse health and social implications for women, children, the community and the environment, result in greater expenditure on national health care provision, and increase inequalities in health. The Global Strategy for Infant and Young Child Feeding, adopted by all WHO member states at the 55th WHA in May 2002 provides a basis for public health initiatives to protect, promote and support breastfeeding. The 2005 Innocenti Declaration further highlights the key actions urgently needed to ensure the best start in life for children and for the realisation of human rights of present and future generations.

Extensive experience shows that breastfeeding can be protected, promoted and supported only through concerted and coordinated action. This Blueprint for Action, written by breastfeeding experts representing all EU and associated countries and relevant stakeholder groups, including mothers, is a model that outlines the actions that a national or regional plan should contain and implement. It incorporates specific interventions and sets of interventions for which there is an evidence base of effectiveness. It is hoped that the application of the Blueprint will achieve a Europe-wide improvement in breastfeeding practices and rates (initiation, exclusivity and duration); more parents who are confident, empowered and satisfied with their breastfeeding experience; and health workers with improved skills and greater job satisfaction. This is in line with the actions envisaged by the 2nd WHO European Action Plan for Food and Nutrition Policy 2007-2012.

Prevailing budgets, structures, human and organizational resources will have to be considered in order to develop national and regional action plans based on the Blueprint. Action plans should build on clear policies, strong management and adequate financing. Specific activities for the protection, promotion and support of breastfeeding should be supported by an effective plan for information, education and communication, and by appropriate pre- and in-service training. Monitoring and evaluation, as well as research on agreed operational priorities, are essential for effective planning. Under six headings, the Blueprint recommends objectives for all these actions, identifies responsibilities, and indicates possible output and outcome measures.

Policy and planning, management and financing

A comprehensive national policy should be based on the Global Strategy and on the 2nd WHO European Action Plan for Food and Nutrition Policy 2007-2012, and should be integrated into overall national health and nutrition policies. Specific parts of this national policy should address socially disadvantaged groups and children in exceptionally difficult circumstances to reduce inequalities. Professional associations should be encouraged to issue recommendations and practice guidelines based on these national policies and on standard recommendations such as those proposed by the EUNUTNET project. Any such public health and nutrition policies and practice guidelines should be developed free from commercial interference or pressure to avoid any risk that integrity of and public confidence in professional decision-making be undermined by conflicts of interest. Long- and short-term plans should be developed by relevant ministries and health authorities, which should also designate suitably qualified coordinators and inter-sectoral committees. Adequate human and financial resources are needed for implementation of the plans.

Communication for Behaviour and Social Change

Adequate communication for behaviour and social change is crucial for the re-establishment of a breastfeeding culture in countries where artificial feeding has been considered the norm for several years or generations. Communication for behaviour and social change messages for individuals

and communities must be consistent with policies, recommendations and laws, and with practices within the health and social services sector. Expectant and new parents have the right to full, correct and independent infant feeding information, including guidance on safe, timely and appropriate complementary feeding, so that they can make informed decisions. Face-to-face counselling needs to be provided by adequately trained health workers, peer counsellors and mother-to-mother support groups. The particular needs of the women least likely to breastfeed must be identified and actively addressed. The distribution of materials on infant feeding provided by manufacturers and distributors of products under the scope of the International Code of Marketing of Breastmilk Substitutes that is not approved by appropriate government authorities should be prevented.

Training

Pre- and in-service training for all health worker groups needs improvement. Pre- and post-graduate curricula and competency on breastfeeding and lactation management, as well as textbooks, should be reviewed and developed. Evidence-based in-service courses should be offered to all relevant health care staff, with particular emphasis on staff in frontline maternity and child care areas. Manufacturers and distributors of products under the scope of the International Code of Marketing of Breastmilk Substitutes should not influence training materials and courses. Relevant health care workers should be encouraged to attend advanced lactation management courses shown to meet best practice criteria for competence.

Protection, promotion and support

Protection of breastfeeding is largely based on the full implementation of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant World Health Assembly resolutions, including mechanisms for enforcement and prosecution of violations and a monitoring system that is independent of commercial vested interests; and on maternity protection legislation that enables all working mothers to exclusively breastfeed their infants for six months and to continue thereafter. Promotion depends on the implementation of national policies and recommendations at all levels of the health and social services system so that breastfeeding is perceived as the norm. Effective support requires commitment to establish standards for best practice in all maternity and child care institutions/services. At individual level, it means access for all women to breastfeeding supportive services, including assistance provided by appropriately qualified health workers and lactation consultants, peer counsellors, and mother-to-mother support groups. Family and social support through local projects and community programmes, based on collaboration between voluntary and statutory services, should be encouraged. The right of women to breastfeed whenever and wherever they need must be protected. All protection, promotion and support activities should be geared in particular to women less likely to breastfeed and their families.

Monitoring

Monitoring and evaluation procedures are integral to the implementation of an action plan. To ensure comparability, monitoring of breastfeeding initiation, exclusivity and duration rates should be conducted using standardised indicators, definitions and methods. These have not been agreed upon yet in Europe; more work is urgently needed to develop consensus and issue practical instructions on a standard list of indicators, including definitions and methods based on global WHO recommendations to guarantee comparability at international level. Monitoring and evaluation of practices of health and social services, of implementation of policies, laws and codes, of the coverage and effectiveness of communication for behaviour and social change activities, and of the coverage and effectiveness of training, using standard criteria, should also be an integral part of action plans. The results of monitoring and evaluation activities should be used for re-planning.

Research

Research needs to elucidate the effect of marketing practices under the scope of the International Code of Marketing of Breastmilk Substitutes, of more comprehensive maternity protection legislation, of different communication for behaviour and social change approaches and interventions, and in general, of public health initiatives. The cost/benefit, cost/effectiveness and feasibility of different interventions need also further research. The quality of research methods need to substantially improve, in particular with regards to adequate study design, consistency in the use of standard definitions of feeding categories, and use of appropriate qualitative research methods when needed. Ethical guidelines should ensure freedom from all competing and commercial interests; the disclosure and handling of potential conflicts of interest of researchers is of paramount importance.

I. Introduction

The protection, promotion and support of breastfeeding should be a public health priority in Europe because:

- Breastfeeding is the natural way to feed infants and young children. Exclusive breastfeeding for the first six months of life ensures optimal growth, development and health.¹ After that, breastfeeding, with appropriate complementary foods, continues to contribute to the infant's and young child's optimum nutrition, development and health, including prevention of infections, overweight, obesity, cancer and other chronic diseases.²⁻⁶
- Breastfeeding in some health care and social institutions is still not optimally promoted and supported as care practices persist in these institutions that are known to obstruct rather than aid the effective initiation and continuation of breastfeeding.^{7,8} As a result, many children in Europe are still being deprived of the many advantages that breastfeeding has to offer.
- Low rates and early cessation of breastfeeding, particularly within marginalised and poorer communities, have important adverse health and social implications for women, children, the community and the environment, resulting in greater health expenditure and the exacerbation of existing health inequalities.⁹⁻¹¹
- "If a new vaccine became available that could prevent one million or more child deaths a year, and that was moreover cheap, safe, administered orally, and required no cold chain, it would become an immediate public health imperative.

Breastfeeding can do all of this and more, but it requires its own "warm chain" of support - that is, skilled care for mothers to build their confidence and show them what to do, and protection from harmful practices. If this warm chain has been lost from the culture, or is faulty, then it must be made good by health services."¹²

Protection, promotion and support of breastfeeding fall squarely within the domain of human rights. The Convention on the Rights of the Child,¹³ adopted by the UN General Assembly in 1989 and ratified so far by all countries except the USA and Somalia, states in its Article 24 that, "States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health ... States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures ... To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents".

Public health initiatives to protect, promote and support breastfeeding should be founded on the Global Strategy for Infant and Young Child Feeding (Annex I), adopted by all WHO Member States at the 55th WHA in May 2002 and by the Executive Board of UNICEF in September 2002.¹⁴ The Global Strategy builds on the International Code of Marketing of Breastmilk Substitutes¹⁵ and subsequent relevant WHA resolutions (Annex 2);^c the Innocenti Declarations of 1990 (Annex 3);¹⁶ and the WHO/UNICEF Baby Friendly Hospital Initiative (Annex 4).¹⁷ The urgency to act on the objectives of the Global Strategy is further emphasized by the 2005 Innocenti Declaration (Annex 3).¹⁸ The Global Strategy is also consistent with the 1992 FAO/WHO World Declaration and Plan of Action for Nutrition,¹⁹ and with the Ist and 2nd WHO European Action Plans for Food and Nutrition Policy (Annex 5),^{20,21} the objectives of which all Member States in the EU are committed to achieve.

The Global Strategy gives particular consideration to the special needs of children in exceptionally difficult circumstances (low birth weight infants, malnourished children, victims of natural and human-

c The International Code of Marketing of Breastmilk Substitutes and the subsequent relevant WHA Resolutions are jointly referred to in this document as the International Code.

induced emergencies, infants born to HIV-infected women, children of families in difficult situations)

and includes policies for safe, timely and appropriate complementary feeding. It is recommended that EU countries and/or associations based in the EU adhere to the Operational Guidelines on Infant Feeding in Emergencies when they provide humanitarian aid to other countries or nutrition support to refugees and asylum seekers in EU countries.^{22d}

The importance of protecting, promoting and supporting breastfeeding has also been reiterated in important EU documents. The EURODIET project strongly recommended a review of existing activities and the development and implementation of a EU action plan on breastfeeding.²³ Following on from EURODIET, the so-called "French Initiative" on nutrition highlighted the need for action on breastfeeding surveillance and promotion.²⁴ The French Initiative led to the EU Council Resolution on Nutrition and Health in December 2000, where breastfeeding was officially recognised as a priority.²⁵

The protection, promotion and support of breastfeeding has important social and economic, in addition to health, consequences. In many high-income countries, the cost to the health system of treating diseases and conditions preventable by breastfeeding is estimated in several thousands of euros per child per year.²⁶⁻²⁹ To these costs, families must add hundreds of euros for the purchase and administration of formula and for indirect health care costs.^{30,31} Formula feeding has also a heavy impact on the environment, due to agricultural activities around cow milk production, the industrial process of manufacturing and distributing the product, the energy needed to maintain the cycle of production, transport and consumption, and the management of an enormous amount of waste. Finally, breastfeeding is often quoted in the reports to the WHO Commission on Social Determinants of Health as one of the factors that may contribute to the reduction of national and global inequalities.^{32,33}

The Blueprint for Action and its associated documents^{34,35} come as a logical extension of these researches, projects, proposals, resolutions, policies and action plans, and offer a practical tool which seeks to bring to fruition the aspirations of all these initiatives.

Why do we need a Blueprint?

Despite difficulties in interpreting available data, it is clear that breastfeeding rates and practices in EU countries fall short of best evidence-based recommendations.^{2,14} The Global Strategy states: "As a global public health recommendation, infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond."

Extensive experience clearly shows that breastfeeding can be protected, promoted and supported only through concerted and coordinated action. EU countries are currently coordinating action in other health fields and social sectors. Action on breastfeeding in Europe is presently uncoordinated. Not all countries have national policies and plans, and even when these are in place they are sometimes not acted upon, or may not be compatible with universally recognised best evidence-based recommendations.

What is the Blueprint?

The Blueprint is a model plan that outlines the actions a national or regional plan should contain and implement if effective protection, promotion and support of breastfeeding are to be achieved. Underpinning all stages of the action plan is the need for:

- Effective policy, planning, management and financing;
- High quality communication for behaviour and social change;
- · Appropriate pre- and in-service health worker training, with supportive supervision;
- Timely evaluation and monitoring of all initiatives employed.

The Blueprint incorporates specific interventions and sets of interventions; most of the recommended interventions have been previously graded by the level of evidence supporting it.³⁵ The Blueprint also includes interventions which, though not based on research evidence, long-standing experience has shown are necessary for the effective implementation of an action plan.

The Blueprint is put forward as a model to be applied as necessary. Some countries/ regions in Europe may already have well coordinated structures and practices in place that are of a high standard and require little or no further action. Others may have poorly coordinated practices that may or may not be policy driven or evidence based; the necessity to apply the Blueprint's actions in these latter countries/regions is more obvious. Information gathered for this project would indicate that the situation in most European countries/regions lies somewhere between these two scenarios, thereby requiring the careful selection and adaptation of Blueprint actions to address deficits in individual national and regional policies and practices.

The Blueprint does recommend some specific Europe-wide operational strategies, such as those related with the marketing of breastmilk substitutes, with the position of the European Union at the meetings of Codex Alimentarius, and with research. For other strategies, the Blueprint recognizes that Europe-wide strategies would require an integration of a multiplicity of different structures and funding arrangements prevailing across all countries that is not possible in the short term. Operational strategies or action plans based on the Blueprint, therefore, will only be effective at national or regional level when due account is taken of the prevailing budgets, structures, human and organizational resources.

How was the Blueprint developed?

The Blueprint for Action was developed by a group of breastfeeding experts representing all EU and associated countries. Within the group of national respondents to the project most of the key relevant health and allied professional bodies and stakeholder groups were represented, including service-user representatives. Before developing the Blueprint, the group analysed the current situation (prevailing breastfeeding rates and practices) in all the participant countries.³⁴ The group then undertook a thorough review of breastfeeding interventions, together with an analysis of the research evidence supporting them, in order to identify the gaps between what is done and what should be done.³⁵ The draft Blueprint was then submitted for consideration and review by a larger group of stakeholders, identified as having a specific relevant role and expertise in their respective countries. The current version has been revised within the project Promotion of breastfeeding in Europe: pilot testing the Blueprint for Action, as described in the preamble.

To whom is the Blueprint addressed?

The Blueprint is aimed at informing key public health policy makers and governmental bodies concerned with women and children's health, welfare, education and related issues, in the EU and other countries participating in the project. It is also directed at stimulating cooperation between all those persons working in the public and private sector, including NGOs, who play important roles in the protection, promotion and support of breastfeeding. A concise version of the original Blueprint, aimed at informing the general population and the media, is also available.^e

How can the Blueprint be used?

National and regional public health, social and educational authorities are recommended to apply relevant aspects of the Blueprint in the development or revision of their national and regional breastfeeding policies, initiatives and operational plans. The implementation and evaluation of regional and national action plans based on the Blueprint will be the responsibility of the relevant authorities involved, including district and health facility levels. An integral part of this process will be getting commitment from the relevant bodies to work together towards the implementation of the actions proposed. These bodies will include hospital and community health authorities, national and regional Government departments, relevant professional organisations, NGOs, schools, colleges, employer and employee bodies, and many more. Outcome and output measures are also suggested in the Blueprint. Progress and process indicators should be based on these when developing national and regional operational plans.

What difficulties were identified in applying the Blueprint in the project sites?

Policy-makers in some situations were unfamiliar with the Blueprint's subject matter and supporting documentation. This led to misunderstandings regarding, for example, prioritising key actions and their practical application. Health professionals and members of NGOs on the other hand did not always understand the management and financial perspective of policy makers and planners. Some problems were also identified with the formatting of the original Blueprint, which made it difficult to follow or apply sequentially, and these were addressed. This applied especially to the section on monitoring; users considered that it was better to integrate the indications on what outcome and output should be monitored, and by whom, in each activity table, rather than in a separate section, while leaving the text as it was in the original Blueprint.

What is the expected outcome for the Blueprint?

It is hoped that the application of the Blueprint will result in:

- Europe-wide improvement in breastfeeding practices and rates (with major increases in initiation, exclusivity and duration rates);
- A significant increase in the number of parents who are confident, empowered and satisfied with their breastfeeding experience;
- Improved skills in promoting, supporting and protecting breastfeeding, thus enjoying greater job satisfaction, for the vast majority of health workers.

The attainment of these expected outcomes will entail the implementation of a series of national and local breastfeeding action plans adequately resourced and regularly reviewed and updated as required.

The Blueprint recognizes that mothers who decide to artificially feed their infants, having received full, correct and optimal infant feeding information, should be respected in their decision, and should get all the infant feeding help and support they require, including expert information on what, when and how complementary foods should be given. Because bonding and nurturing imply more than feeding, any support to mothers should extend beyond feeding, to foster the establishment of an optimal relationship with the child.

II.

A summary of the situation in the 29 countries surveyed at the beginning of the first Blueprint project can be found in the original Blueprint; more details were published in a public health journal,³⁶ and the full document is available online.^g The same survey was carried out at the end of 2007 during this project. The questionnaire was sent to the same 29 countries and was returned by the representatives of 23 countries: Austria, Czech Republic, Germany, Denmark, Greece, Spain, Finland, France, Iceland, Ireland, Italy, Lithuania, Luxembourg, Latvia, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovak Republic and United Kingdom (England, Wales, Scotland and Northern Ireland). The following is a summary of the main conclusions that can be drawn:

- As far as data collection for monitoring breastfeeding rates is concerned, things did not change much between 2002 and 2007. The definitions and methods used are still far from being standardised across and within countries, making comparisons as difficult in 2007 as they were in 2002. Moreover, only a few countries had in 2007 national data that updated those reported in 2002.
- Improvements in the rates of initiation of breastfeeding are reported from Ireland, France and the UK, i.e. the countries in which rates were very low in 2002 and continue to be lower than elsewhere in Europe in 2007. Higher rates of exclusive breastfeeding at six months are reported from the Netherlands and the Slovak Republic, while rates are apparently decreasing in Austria; this, however, is an artefact due to a change of definition between surveys. The rate of any breastfeeding at six months has gone up in Finland and to a lesser extent in the Netherlands and Portugal. As far as breastfeeding at 12 months is concerned, the only country reporting an improvement is Austria.
- The statement made in 2002 that breastfeeding rates and practices in EU countries fall short of WHO and UNICEF recommendations, and of targets and recommendations proposed in national policies and by professional organisations, holds true. Even in countries where initiation rates are high, there is a marked fall-off in breastfeeding in the first six months. The exclusive breastfeeding rate at six months is lower than recommended throughout Europe.
- The number of countries with good national policies has increased, and in particular the number of countries where exclusive breastfeeding is recommended up to six months. Only six out of 23 countries lacked a national policy in 2007, compared to 11 out of 29 in 2002. Eleven countries report updates in their practice guidelines on breastfeeding to meet the standards set by the Global Strategy. This process may have been boosted by the publication of the standard recommendations developed within the EUNUTNET project and endorsed by many professional associations.³⁷ Finally, eight countries, including four of those that participated in the project for pilot testing the Blueprint for Action, developed or revised their national plans of action during this period, bringing the total number of EU countries with such a plan up to 18 out of 24, compared to 13 out of 29 in 2002.
- Some countries have yet to achieve the goals and the objectives set for 1995 by the 1990 Innocenti Declaration. The proportion of countries with a national committee has gone up from 69% in 2002 to 79% in 2007, but no such improvement is reported in the proportion of countries with a national coordinator. Little improvement is also reported in terms of financial support to national committees and coordinators. The additional actions urged in the 2005 Innocenti Declaration do not appear to have accelerated the process of change.
- Except for Austria and Finland, the number of Baby Friendly Hospitals and the proportion of infants born in Baby Friendly Hospitals has increased everywhere. Greece and Iceland are the only two countries without Baby Friendly Hospitals. Sweden is the only country where all hospitals are Baby Friendly, but the number of countries where more than 50% of infants are born in these hospitals has gone up from three to five, and there is an overall upward shift in the distribution of countries by this indicator. The Baby Friendly Hospital Initiative is certainly the field in which more

 $g \ see \ http://ec.europa.eu/health/ph_projects/2002/promotion/fp_promotion_2002_a1_18_en.pdf$

improvements are reported in 2007 compared to 2002, as testified by the fact that all countries have a BFHI coordinator, compared to 20 out of 29 in 2002. Moreover, many countries are engaged in other Baby Friendly initiatives such as those addressing primary health care services, paediatric wards, neonatal intensive care units and schools for health professionals. The number of large teaching hospitals that are designated as Baby Friendly, however, remains low, while pre-service training still appears to be inadequate.

- On the other hand, the coverage with in-service training using quality-assessed courses is
 increasing.All countries except Ireland and Lithuania have introduced the 18-hour UNICEF/WHO
 course on breastfeeding practices and/or the 40-hour WHO/UNICEF course on counselling, or
 adapted versions of these courses. In some countries (e.g., Denmark, Norway, Sweden), however,
 these courses are considered too basic.The number of IBCLC is also increasing in most countries,
 indicating the need for expert lactation consultants.
- No changes are reported for the legislation on maternity protection and on marketing of breastmilk substitutes. This is understandable, as such changes usually occur over longer periods of time and often depend on international and EU conventions and directives. As far as the International Code is concerned, most countries apply the EU Directive of 1991,³⁸ which does not cover all its provisions. In December 2006 the European Commission issued an updated Directive;³⁹ this will not make a substantial change towards the application of all the provisions of the International Code. Meanwhile, some countries carried out surveys to monitor compliance with the Code and found that violations are systematic.
- In most countries, the legislation on maternity protection with relevance to breastfeeding goes beyond the minimum standards recommended by the ILO 183 Convention,⁴⁰ even though only eight EU countries ratified it so far: Austria, Bulgaria, Cyprus, Hungary, Italy, Lithuania, Romania and the Slovak Republic. Where national legislation does not meet the ILO standards, it is mainly due to the lack of provisions for lactation breaks. Moreover, many categories of working mothers (e.g., women employed for less than 6-12 months at the time of application for maternity leave, contract workers, irregular part-time workers and apprentices/working students) are not covered by the legislation in many countries. Finally, most national legislations have not been adapted to allow mothers to fully implement the infant and young child feeding recommendations of the Global Strategy.
- All countries report the existence of peer counsellors and mother-to-mother support groups and
 organisations; their number is generally increasing, as well as the coverage of the services they
 provide, though this is estimated as medium to high only in about half the countries. The degree
 of co-ordination among these groups is slowly improving, as well as the degree of integration and
 co-ordination with the relevant statutory services. Funds for communication activities are also
 increasing, with a consequent increase in the production of materials (i.e., booklets, leaflets, videos
 and campaigns), including those used for the World Breastfeeding Week.

III. Determinants of breastfeeding

For an action plan to be effective and feasible it must take due account of the determinants of breastfeeding. Determinants should be considered also when designing protocols for monitoring breastfeeding attitudes, practices and rates. Their different spheres of influence imply that their effect needs to be monitored and addressed through national policies as well as at health service level and in society generally. Many of the determinants of breastfeeding may act in different directions depending on specific local situations. For example, maternal education and employment may be associated with longer or shorter duration of breastfeeding in different populations. The determinants of breastfeeding at least of be below shows one of the possible categorizations and a list of determinants known to influence breastfeeding initiation and duration.⁴¹

Mother, child, family	• Age, parity, physical and psychological health of the mother	
	• Breastfeeding experience of the mother herself, and with previous children	
	Education, employment, social class, ethnicity, area of residence	
	• Knowledge, attitudes, confidence in the ability to breastfeed	
	• Marital status, family size, support from father/partner and family	
	• Lifestyles (smoking, alcohol, drugs, diet, physical exercise)	
	• Birth weight, gestational age, mode of delivery, health of the newborn	
	• Access to role-models who have had positive breastfeeding experiences	
Health care system	Access to antenatal care and quality of care	
	• Quality of assistance during delivery and in the first few days	
	Access to postnatal maternal and child health care, and quality of care	
	• Type and quality of professional support for lactation management	
	Access to peer counselling and mother-to-mother support	
Public health policies	• Level of priority and financial support given to breastfeeding	
	Official policies, recommendations and plans	
	Breastfeeding monitoring and surveillance systems	
	• Quality of pre- and in-service training of health workers	
	• Financial support for voluntary mother-to-mother support activities	
	CBSC and use of different media for breastfeeding advocacy	
Social policies	Legislation on and enforcement of the International Code	
and culture	• Legislation on maternity protection and its enforcement	
	• Representation of infant feeding and mothering in the media	
	 Obstacles and barriers to breastfeeding in public 	
	• Prevalence and activities of mother-to-mother support groups	
	Level of community awareness and knowledge	

Determinants have also been categorized as follows:⁴²

- Demographic, social and economic characteristics of the mother and family.
- Structural and social support.
- Health and risk status of mothers and infants.
- Mother's knowledge, attitudes, skills.
- Aspects of the feeding regime/practices.
- Health services organization, policies and practices.
- Cultural, social, economic, commercial and environmental factors.

IV. Overview of the review of interventions^h

Interventions for the protection, promotion and support of breastfeeding, as with any other health care and public health intervention, should ideally be based on evidence of effectiveness. The review of interventions carried out by the initial project took into consideration, in addition to controlled studies, reports of successful experiences. The Project recognised that many aspects of the protection, promotion and support of breastfeeding, in particular those not specifically related to the health care sector, are not amenable to the rigorous evaluation of effectiveness implicit in the concept of evidence-based medicine. The interventions were then categorised under policy and planning; communication for behavioural and social change; training; and protection, promotion and support of breastfeeding. In each category, interventions were graded by quality of the evidence base.

The review leads to the following conclusions on effective interventions:

- The combination of several evidence-based strategies and interventions within multi-faceted integrated programmes seems to have a synergistic effect.
- Multi-faceted interventions are especially effective when they target initiation rates as well as duration and exclusivity of breastfeeding, using media campaigns, health education programmes adapted to the local situation, comprehensive training of health workers and necessary changes in national/regional and hospital policies.
- The effectiveness of multi-faceted interventions increases when peer support programmes are included, particularly in relation to exclusivity and duration of breastfeeding.
- Interventions spanning the pre- and post-natal periods, including the crucial days around childbirth, seem more effective than interventions focussing on a single period. The BFHI is an example of a wide-ranging intervention of proven effectiveness, and its extensive implementation is highly recommended.
- Health sector interventions are especially effective when there is a combined approach, involving the training of staff, the appointment of a breastfeeding counsellor or lactation consultant, having written information for staff and clients, and rooming-in.
- The impact of health education interventions to mothers on initiation and duration of breastfeeding is significant only when current practices are compatible with what is being taught.
- The provision of breastfeeding information to prospective parents or new mothers, with no or brief face-to-face interaction (i.e. based on leaflets or telephone support), is less effective than the provision of information with extended face-to-face contact. The use of printed materials alone is the least effective intervention.
- The effectiveness of programmes which expand the BFHI beyond the maternity care setting to include community health care services and/or paediatric hospitals, currently being implemented in some countries, has so far not been evaluated. However, these programmes are based on a combination of initiatives that on their own are well evidence-based.
- The development and enforcement of laws, codes, directives, policies, and recommendations at various levels (national, regional) and in various situations (workplace, hospital, community) represent important interventions, however it is currently difficult to gather strong evidence for their effectiveness (few studies, mainly within multifaceted interventions).
- Workplace interventions are especially effective when mothers have the flexibility to opt for part-time work and have guaranteed job protection along with provisions for workplace breastfeeding/lactation breaks. These provisions, whether in response to a legislative requirement or as part of a breastfeeding supportive workplace policy, involve time off without loss of pay during the working day to breastfeed or express breastmilk, with suitable facilities being provided by the employer.

After the completion of the above-mentioned review, other reviews of and guides to interventions were published.⁴³⁻⁴⁶ Overall, these updated reviews and guides confirmed the results of the review carried out within the Blueprint project.

The decision to implement a set of interventions needs to consider feasibility and cost, in addition to effectiveness. Feasibility and cost are country and area specific because they depend on local economic, social and cultural conditions. Political commitment is more fundamental to the successful implementation of breastfeeding interventions than feasibility and cost issues. It is recognised that in an ideal situation, where cost is not the primary determinant, a public health intervention with a higher cost may be deemed feasible based on economies of scale and a more favourable ratio of benefit to cost. Some strategies and interventions may be recommended even if they are not strongly evidence-based; this applies in particular to legislation and general policies that are not easily amenable to rigorous scientific evaluation. However, expert opinion and experience show that these initiatives do have long-term benefits on the number of mothers successfully breastfeeding.

Finally, a programme for the protection, promotion and support of breastfeeding is not just a list of separate interventions. Interventions are usually multifaceted, interrelated and integrated in order to maximise their combined and cumulative effect. Moreover, the effect will depend on continuity, because a change in the behaviour of mothers, families and health workers, and of the infant feeding culture in a given society, requires that interventions and programmes be sustained for a sufficient length of time.

V. The Blueprint for Action

I. POLICY AND PLANNING, MANAGEMENT AND FINANCING

Analyse the situation

The policy and planning process, be it to develop a new plan or to revise an old one, usually starts from an analysis of the situation. The participants in the pilot project found the application of an idea originated in Scotland useful. This implies using the Blueprint as a template, or as a checklist, with space for comments, to determine the number of recommended objectives already fully or partially achieved and to list those that are not or partially achieved (Annex 7).

Develop a policy

A policy is a series of statements that define the actions that a national or local public authority decides to put into practice to address a matter of public health concern, such as achieving optimal infant and young child feeding. Some countries already have their own policy. Other countries may not yet have developed a policy or may need to revise it, before or while they develop their plan of action. Annex 8 presents a model policy document. Countries will obviously need to adapt this model to their specific situations. Once adopted, the policy will be communicated to all health and relevant allied workers caring for mothers, infants and young children. A policy will usually be revised every 3-5 years, or earlier if new evidence warrants it. Monitoring of implementation is essential.

Issue practice guidelines

Practice guidelines are needed to implement the statements and the expressions of intents represented by the policy. Again, some countries may already have their practice guidelines, while other countries may need to start from scratch or to revise or update their old guidelines. The participants in the pilot project found the standard recommendations developed by the EU-funded project EUNUTNET useful for this purpose.³⁷¹ As any other document of this kind, these recommendations will also need local adaptation, in addition to regular updating based on available evidence. Needless to say, practice guidelines should be developed in collaboration with all professional associations involved in infant and young child feeding.

Planning

Comprehensive national/regional plans addressing effective protection, promotion and support of breastfeeding should be developed based on the Global Strategy and on the "Planning Guide for national implementation of the Global Strategy for Infant and Young Child Feeding".^j All plans on breastfeeding, or better on infant and young child feeding, should be integrated into overall public health policies and plans, with specific emphasis on the needs of socially disadvantaged communities.

Set priorities

In a plan, the list of objectives to be achieved may be short or long. While all these objectives may be included in a long-term plan, it is very unlikely that all will be included in a short-term plan. Hence the need to set priorities. This exercise will yield varying results depending on local situation and resources, as shown by the plans developed in the countries where the Blueprint was pilot tested. It is impossible to dictate what process should be used for setting priorities. Some principles, however, can be laid down:

- 1. Identify relevant stakeholders, keeping in mind principles for avoiding and managing conflicts of interest, and involve them.
- 2. Share with stakeholders the list of all the possible objectives to include in the plan.
- 3. Agree with involved stakeholders on criteria for priority setting, e.g.:
- Magnitude or frequency of the problem (number of people affected);

i These recommendations are available for download at http://www.burlo.trieste.it/?M_Id=5/M_Type=LEV2 and also in the website of the International Lactation Consultant Association at ilca.org/liasion/Infant-and-YoungChildFeeding/EUPolicy06English.pdf. The document is available also in other EU languages.

- Likelihood of success or of positive outcome (effectiveness of interventions);
- Acceptability (or desirability) for politicians, managers, professionals, public;
- Equity (i.e. likelihood that an achieved objective will reduce inequalities);
- · Feasibility and cost given available resources.
- 4. Decide what score and weight system will be used for each agreed criterion.
- 5. Gather the information needed to score objectives based on agreed criteria.
- 6. Provide the available information to all the involved stakeholders.
- 7. Establish a timeline and a deadline for feedback and decision-making.
- 8. Gather from stakeholders scores and ranks for the agreed list of possible objectives.
- 9. Reach an agreement on the manageable number of objectives to be included in the plan.

10.List the selected objectives and verify that there is a consensus.

Define objectives and write a plan

The priority objectives identified in the previous step need to be translated into specific operational objectives and activities. For this purpose, for each objective:

- A time frame has to be established.
- Measurable outputs and outcomes, with clear definitions, have to be identified.
- A person responsible and accountable for implementation should be indicated.
- An outline on how implementation will occur should be agreed upon.
- · The resources needed for implementation should be identified.

Some objectives may encompass two or more secondary objectives that will also need to be translated into operational objectives and activities, as described above. The operational tables of Section VI give guidance on possible people and/or institutions to be held responsible for different objectives, either because of their role or after agreement has been reached among all those involved.

Primary and secondary objectives should indicate as specifically as possible the desired outputs and outcomes, including timing. Whether targets to be periodically achieved should be added, is a matter for discussion. In many places, targets are used to reward and encourage people; more rarely, targets may be used to punish. While the latter use of targets should be proscribed, the former may have some beneficial effect,⁴⁷ and may be welcome especially by health professionals in the lower salary range. Objectives and targets, however, should always be used as means and never as ends.

Planning by objectives is not an exact science and one should never consider an objective as untouchable. It might have been wrongly chosen in the first place, it might have been wrongly developed and/or implemented, or the situation might have changed due to intrinsic or extrinsic factors thereby making the objective inappropriate or obsolete. Planners and managers must be ready to review and redefine their set of objectives, actions and activities as required. Hence the importance of good management and monitoring.

Management and financing

Management can be defined as a set of activities aimed at achieving a predetermined objective. The main functions of management are:

- Decide what should be done, where, when and by whom.
- Ensure that each activity is performed by the person with the right skills.
- Make sure that the resources needed to implement activities are available.
- Supervise activities to ensure that the performance meets given standards.
- Create and/or sustain good relationships among the people working in the same team.
- Coordinate the activities performed by different people and teams to avoid contrasts and overlaps, and facilitate communication.

- Analyse the gaps between planned and actual activities to re-plan.
- Ensure that the information needed for monitoring is gathered and regularly analysed.

A good manager (e.g., the national or local breastfeeding coordinator) should always be aware of the fact that material resources, including money, are renewable. There are, however, two special kinds of resources that can not be renewed: time and people. These are the resources that need special care, the latter in particular because it is only people that make things happen. A set of skills that a manager should have and/or develop are negotiation skills, i.e. the capacity to improve the involvement of all stakeholders and people engaged in implementation of activities.

Managing people is more complex than managing things. Efficient ways of working and regular salaries are not enough to keep people satisfied. The work must be interesting and stimulating. The working environment and the relations among professionals and with users must be kind, if not pleasant. To achieve this, it is important to:

- Share objectives;
- Facilitate good personal relations;
- Delegate and distribute tasks, including authority and responsibility;
- Coordinate activities with appropriate channels of communication;
- Help with personal problems;
- Resolve disputes among team members;
- Provide opportunities for training and update.

Given the critical public health need to improve breastfeeding rates throughout Europe, sufficient investment from relevant state and federal organisations should be made to ensure that the health sector and voluntary breastfeeding support NGOs have the resources necessary to realistically achieve significantly better uptake, exclusivity and duration rates for breastfeeding.

All activities (planning, implementation and monitoring) should be carried out in compliance with the International Code and subsequent relevant WHA resolutions, and with the obligations and responsibilities listed in the Global Strategy and the 2005 Innocenti Declaration.

Monitoring a plan

The term evaluation refers to the achievement of an objective or set of objectives. Monitoring refers to the continuous or periodic assessment of activities carried out to achieve an objective. Monitoring, therefore, does not deal with effectiveness or results; it deals with processes (though one can say that many processes are the result of other processes). In some way it deals also with efficiency and appropriate use of resources.

Monitoring means watching:

- the availability, consumption and use of resources, including money;
- the quantity and quality of activities;
- the timeliness of activities.

Log books, store cards, accounts ledgers, duty rosters, checklists, timetables and standards, nowadays often available in electronic formats, are the tools that a manager will use for his/her monitoring function. Each country and region, and often each single institution, has its own set of such tools.

Monitoring can be continuous or periodic, depending on the activity to be monitored. The periodicity will also be established case by case. A cycle of monitoring will be completed with a short report. It is very important to share this report with all the members of the team, if monitoring has to lead to

better performance and higher likelihood of achieving objectives. The report should also be fed back to policy and decision makers at the immediate upper level and, when applicable, to users or their representatives.

2. COMMUNICATION FOR BEHAVIOUR AND SOCIAL CHANGE

Adequate CBSC is crucial for the re-establishment of a breastfeeding culture in countries where artificial feeding has been considered the norm for several years or generations. Breastfeeding is the normal and optimal way to feed and nurture infants and young children, and should be portrayed universally as such by presenting exclusive breastfeeding for six months and continued breastfeeding up to two years and beyond as achievable and desirable in all written and visual materials. CBSC messages for individuals and communities must be consistent with policies, recommendations and laws, as well as consistent with practices within the health and social services sector.

CBSC for individual women and their families

Expectant and new mothers have the right to full, correct and independent information about breastfeeding, including guidance on safe, timely and appropriate complementary feeding, so that they can make informed decisions. Face-to-face counselling needs to be provided by adequately trained health workers, peer counsellors and mother-to-mother support groups. Family and kinship members, e.g. infant's father or mother's partner, infant's grand-parents should also be included in the counselling. The particular needs of women least likely to breastfeed (e.g. women from immigrant communities, adolescent and single mothers, women in poverty and less well-educated women, etc) must be identified and their particular information and skill needs actively addressed.

The distribution of materials on infant and young child feeding provided by manufacturers and distributors of products under the scope of the International Code that is not approved by appropriate government authorities should be prevented for the obvious conflict of interest. Mothers using powder infant formula should be informed that this is not a sterile product and that special precautions are needed for its preparation, storage and handling.⁴⁸

CBSC for communities

It may be useful in CBSC aimed at communities, and in some circumstances also at individual women and their families, to include information on why breastmilk is used in assessing levels of environmental contamination. When such surveys are conducted, the aim is to provide the basis for possible sourcedirected measures to ultimately reduce the levels of Persistent Organic Pollutants in human milk in a way that is consistent with the promotion of human milk as the optimal food for infants.^k In the revised 2007 protocol for the 4th WHO-Coordinated Survey of Human Milk for Persistent Organic Pollutants, WHO, in cooperation with the United Nations Environment Programme, states: "WHO can now say with full confidence that breastfeeding reduces child mortality and has health benefits that extend into adulthood. On a population basis, exclusive breastfeeding for six months is the recommended feeding mode for the vast majority of infants, followed by continued breastfeeding with appropriate complementary foods for up to two years or beyond".¹

The availability, standard and effectiveness of CBSC materials and activities should be regularly monitored and evaluated. Media portrayals of infant and young child feeding should be monitored and media organisations should be guided and encouraged to depict and promote breastfeeding as normal, achievable and desirable. Breastfeeding knowledge, attitudes and behaviour at societal level should also be monitored so as to take a more informed approach to effectively promoting, supporting and protecting it.

k see http://www.who.int/foodsafety/chem/POPprotocol.pdf l see http://www.who.int/foodsafety/chem/POPtechnicalnote.pdf

3. TRAINING

Pre-service training

In general, both pre- and in-service training on infant and young child feeding for all health worker groups, including pharmacists, need improvement. Pre- and post-graduate curricula (including prescribed textbooks/materials) and educational standards should be reviewed/developed to ensure the levels of competency achieved in breastfeeding and lactation management meet best practice standards. A breastfeeding strategy that addresses the pre-service competencies of future health service graduates to effectively promote, support and protect breastfeeding would have the long term effect of improving the quality of support for breastfeeding and thereby reduce the expenditure on in-service training.

In-service training

The need for in-service training may reduce in time but there will always be a need for up-dates as new research knowledge emerges. Currently the WHO/UNICEF models meet the best evidence based standards for breastfeeding training.⁴⁹⁻⁵¹ Further improvements can be obtained by the use of process-oriented training, leading to changes in attitudes of health professionals associated with better counselling and continuity of care.^{52,53}

Priority should be given to ensuring all frontline health workers providing maternity and child care services are enabled to attend effective breastfeeding knowledge and skills training. Training should adequately cover recognized best practice standards and should include a practical skills element. It should also cover the risks of formula feeding and the safety measures to be put in place to reduce these risks and ensure safety, especially when powder infant formula is used.^{48 m}

Manufacturers and distributors of products under the scope of the International Code should not be involved in the provision of materials, training or the awarding of sponsorship or other types of financial support for health service training at institutional or individual level.⁵⁴ Monitoring the effectiveness and availability of courses should underpin the provision of breastfeeding education and training.

Health workers in key service areas should be encouraged and supported to undertake advanced lactation management courses meeting best practice criteria for competence, and e-networking amongst breastfeeding specialists should be facilitated to increase and disseminate knowledge and skills.

4. **PROTECTION, PROMOTION AND SUPPORT**

Global Strategy for Infant and Young Child Feeding

m see http://www.who.int/foodsafety/publications/micro/pif2007/en/

The promotion of breastfeeding as the normal method of feeding infants and young children should be at the core of all national/regional breastfeeding policies and recommendations based on the Global Strategy and reaffirmed in the Innocenti Declaration 2005. The dissemination of these policies to all health professional groups, academic health professional colleges, NGOs and the general public together with an action plan for implementing the policy will ensure widespread 'buy-in' and improve its potential for success.

The approach taken in promoting breastfeeding outside the health sector will be dependent on the prevalence of breastfeeding and the research-identified attitudes and behaviours associated with it at regional and national levels. For example, if culturally-specific research identifies that most people form their opinions about infant feeding long before they even consider becoming parents,

then promotional information needs to be introduced early while these opinions are being formed. Promotional campaigns at societal level and as part of health education programmes during school years can help address this issue. Sophisticated multi-media promotional campaigns can address myths around infant feeding and break down barriers to the universal acceptance and support for breastfeeding. Interventions to promote breastfeeding, whether targeted at the health sector, school children or at whole societal level, must be evaluated to ensure cost-effectiveness.

The International Code

Implementing the International Code into national legislative frameworks, together with mechanisms for monitoring compliance and prosecuting violations, is an essential requirement for the protection of breastfeeding from aggressive commercial marketing practices.

Breastfeeding policies at national and local level should ensure that health professionals and health service providers are well informed about and fulfil their responsibilities under the International Code.

A professional code of ethics covering the responsibilities of health service institutions and individual health workers to protect breastfeeding should be developed covering conflicts of interest in relation to the acceptance of commercial sponsorship for courses, educational materials, research, conferences and gifts, and highlighting how these and other such practices can adversely affect breastfeeding.

Information on the aims and provisions of the International Code together with methods of monitoring compliance and censuring violations should also be disseminated to the general public.

Free formula milk schemes for all, but especially for disadvantaged groups, should be stopped and replaced with assistance that supports breastfeeding. In addition, parents of infants and young children fed with powder formulae should be warned, through appropriate messages on product packaging, that these products are not sterile and need safe handling.³⁴

Legislation for working mothers

Returning to work outside the home is another identified barrier to the up-take and continuation of breastfeeding. National maternity protection legislation should address this barriers to breastfeeding by extending the range (e.g. to include part-time, casual workers, students, etc) and duration of maternity leave and workplace breastfeeding break entitlements to enable women in the workforce to achieve optimal breastfeeding duration rates in line with health service recommendations. There should be widespread dissemination of information on entitlements under Maternity Protection and Health and Safety at Work legislation based on the minimum requirements set by the ILO Maternity Protection Convention 183. However, protection of breastfeeding among working mothers goes beyond legislation and involves the capacity to express, store and administer breastmilk, support by partners and families, and a positive attitude across all sectors of a society.

Baby Friendly Hospital Initiative

Within the health care sector, effective support requires commitment to establish standards for best practice in all maternity and child care institutions and service areas. The BFHI is currently considered the best model for expert practice.ⁿ Adequate resources (funds, personnel/time) and technical support for training, assessment and re-assessment of hospitals participating in the BFHI should be ring-fenced and guaranteed annually. All maternity and paediatric hospitals should be supported and encouraged to become Baby Friendly and those not already participating in the BFHI should nevertheless be expected to put in place the 10 Steps as these represent current best practice. Achieving the standard for full Baby Friendly designation should be incorporated into standard health service quality accreditation systems and in nationally recognized practice guidelines.

In many countries mothers are discharged from hospitals after a couple of days, before breastfeeding is well established. Some countries are therefore adapting the BFHI to primary health care settings. Step 10 of the BFHI should be implemented, but may not be enough to provide a consistent high quality support service across all statutory and voluntary health sectors. This can be achieved by improving cooperation between hospitals and other health and social care facilities and mother-to-mother/peer groups, and extending the range of these services. Adapting the BFHI for application in health care facilities other than maternity hospital (e.g. community health and social service centres, paediatric hospitals, pharmacies and workplaces) will extend and improve the consistency and quality of support services.

The optimal protection, promotion and support of breastfeeding is facilitated by the adoption of normal physiological birthing practices and keeping medical interventions, including pharmacological analgesia during labour,⁵⁵ to a minimum. Initiatives other than those based on the BFHI may also support best practice, but need to be evaluated for effectiveness.

Support by trained health workers

While breastfeeding protection and promotion are fundamental to any breastfeeding policy, it is important that an equal or greater commitment is given to developing support services to ensure that every mother who plans to breastfeed will have ready access to the supports she needs to achieve her objectives and to breastfeed for as long as possible or as long as she wishes. Furthermore, if there is an emphasis on breastfeeding protection and promotion, then adequately and ethically funded support services should be in place and readily available to meet the anticipated extra demand for these services.

Effective support at individual level means that all women should have access to infant and young child feeding supportive services. These services include assistance from appropriately qualified health workers and lactation consultants, peer counsellors, and mother-to-mother support groups. Peer counsellors and mother-to-mother support groups play an important role. This role, however, is greatly facilitated where the structure, routines and procedures, counselling in particular, within antenatal care, maternity, neonatal and paediatric wards, as well as well-baby clinics and other services responsible for follow-up after discharge, consider breastfeeding as a priority and are organised in a Baby Friendly way.

All women should have access to effective support. Women with particular breastfeeding difficulties should have also timely access to expert help and support from appropriately qualified lactation consultants or health workers with equivalent expertise. Women who stop breastfeeding before they wanted or planned to should be encouraged and assisted to examine the reasons for this to help reduce feelings of loss and failure and ensure this experience does not adversely affect any future infant feeding experiences.

Vital support geared toward the specific requirements of mothers of ill or preterm infants is needed, to ensure their lactation is maintained and they are able to supply sufficient expressed breastmilk (plus information on the safe handling and storage of expressed breastmilk) while their babies are unable or too ill to breastfeed. This support should include the provision of breast pumps and assistance with travel and accommodation to ensure they can be near or with their babies as much as possible. These criteria will hopefully form the basis for the development of a BFHI for neonatal units.

Donor breastmilk is a better alternative to breastmilk than formula and access to supplies of safe donor breastmilk should also be available where necessary. In providing support for women who choose not to breastfeed it is important to inform these mothers that powdered infant formula is not a sterile product and as such has inherent risks associated with it. Information on how to minimise this and other risks should be given, based on risk assessment and guidelines developed by WHO.^{48,56}

Regular patient satisfaction surveys should be undertaken to audit the effectiveness of support services in meeting the needs of patients/clients. These surveys should include mothers who choose not to breastfeed to ensure that their choice is respected and facilitated.

All mothers should receive appropriate information on what, when and how to introduce complementary foods to meet their children's evolving nutritional needs, and on how to continue breastfeeding along with adequate complementary feeding.

HIV-positive pregnant women should receive expert unbiased, evidence-based infant feeding information regarding the transmission risks and their options. Their decision in relation to infant feeding should be supported and respected. Further information regarding infant feeding options for HIV-positive pregnant women can be found in the latest Consensus Statement.⁵⁷⁰

Support by trained peer counsellors and mother-to-mother support groups

The availability of support services provided by trained peer counsellors and mother-to-mother support groups should be supported and extended to ensure that all women have ready access to these, especially in communities where breastfeeding rates are low. Course curricula (contents, methods, materials, time) for peer counsellor and mother-to-mother support training should be developed/reviewed and supported. The role of peer counsellors and mother-to-mother support groups can be greatly enhanced by strengthening the cooperation and communication with health workers based in different health facilities.

Support in the family, community and workplace

Collaborative projects involving voluntary and statutory services offering both expert and peer support to breastfeeding families and their social networks are to be encouraged. Supporting and protecting the right of women to breastfeed their babies whenever and wherever the need arises is fundamental. National and local initiatives which promote social acceptability of breastfeeding outside the home should be encouraged. If needed, governments should be urged to put in place legislation which protects a mother's right to breastfeed in public. All these initiatives should address specifically the needs of women less likely to breastfeed, such as primiparae, immigrants, adolescents, single mothers and less educated women, and their families.

5. MONITORING

Monitoring and evaluation procedures should be central to the implementation of an action plan; the results of monitoring and evaluation activities should obviously be used for re-planning. To ensure comparability, monitoring of breastfeeding initiation, exclusivity and duration rates should be conducted using standardised definitions and universally accepted data collection methods. Table I shows the definitions of breastfeeding to be used in cross sectional sample surveys on infant and young child feeding recommended in 1991 by WHO.^{58,59} As these WHO categories do not allow for finer distinctions, monitoring systems or local/regional surveys may wish to use additional categories, which must be clearly defined, to more accurately reflect the prevailing situation. However, for international comparative purposes, it is essential that agreement is reached on applying the WHO categories to a minimum set of indicators.

Data on the above categories of feeding can be gathered at any age. For instance, data could be gathered at 48-72 hours after birth (recall period: from birth), whether birth occurs in hospital or

at home, and at 3, 6, 12 and 24 months of age (recall period: previous 24 hours; it is considered more difficult for mothers to have accurate recall of their infants' diets over longer periods of time). Collecting infant and young child feeding data should be incorporated into existing child health information systems.

Data collection can be whole population-based, i.e. incorporated into existing national or regional maternal and child health and welfare monitoring processes. Data collection can also be population representative survey-based, with surveys conducted at regular intervals. In these latter cases, the samples must be representative of the target population, and the sample sizes must be calculated to allow comparisons between population subgroups and subsequent surveys.

Category of infant feeding ¹	Requires that the infant receive	Allows the infant to receive	Does not allow the infant to receive
Exclusive breastfeeding (EBF)	Breastmilk, including expressed breastmilk or from a wet nurse	Drops, syrups (vitamins, minerals, medicines)	Anything else
Predominant breastfeeding (PBF)	As above, as the predominant source of nourishment	As above plus liquids (water, water-based drinks, fruit juice, ritual fluids)	Anything else (in particular, non-human milk, food-based fluids)
Breastfeeding with complementary foods (CBF) ²	Breastmilk and solid or semisolid foods or non- human milk	Any food or liquid including non-human milk	
Non-breastfeeding (NBF)	No breastmilk	Any food or liquid including non-human milk	Breastmilk, including expressed breastmilk or from a wet nurse

Table 1. Definitions of breastfeeding recommended by WHO.

I. The sum of EBF+PBF is called full breastfeeding (FBF). The sum of EBF+PBF+CBF is called breastfeeding (BF). The sum of EBF+PBF+CBF+NBF in a given sample or population must equal 100% as these categories are mutually exclusive.

2. Note: this definition does not distinguish infants and children who take, in addition to breastmilk, formula only, non-human milk only, solid or semisolid foods only, or different combinations and proportions of the above; nor does it take into account the proportion of breastmilk on overall 24-hour food intake.

In 2007, WHO issued a consensus document to propose a new set of indicators on infant and young child feeding for sample cross sectional surveys.⁶⁰ The set includes eight core and seven optional indicators (Table 2), with definitions unchanged compared with 1991, except for a minor detail regarding oral rehydration solutions:

Core indicators	Optional indicators
I. Early initiation of breastfeeding: proportion of children born in the last 23.9 months who were put to the breast within one hour of birth	9. Children ever breastfed: proportion of children born in the last 23.9 months who were ever breastfed
2. Exclusive breastfeeding under six months: proportion of infants 0-5.9 months of age who are fed exclusively with breastmilk ²	 10. Continued breastfeeding at two years: proportion of children 20-23.9 months of age who are fed breastmilk
3. Continued breastfeeding at one year: proportion of children 12-15.9 months of age who are fed breastmilk	I I. Age-appropriate breastfeeding: proportion of children 0-23.9 months of age who are appropriately breastfed ⁶
4. Introduction of solid, semi-solid or soft foods: proportion of infants 6-8.9 months of age who receive solid, semi-solid or soft foods	12. Predominant breastfeeding under six months: proportion of infants 0-5.9 months of age who are predominantly breastfed
5. Minimum dietary diversity: proportion of children 6-23.9 months of age who receive foods from four or more food groups ³	13. Duration of breastfeeding: median duration of breastfeeding among children 0-35.9 months of age ⁷
6. Minimum meal frequency: proportion of breastfed and non-breastfed children 6-23.9 months of age who receive solid, semi-solid or soft foods (also including milk feeds for non- breastfed children) the minimum number of times or more ⁴	14. Bottle feeding: proportion of children 0-23.9 months of age who are fed with a bottle
7. Minimum acceptable diet: proportion of children 6-23.9 months of age who receive a minimum acceptable diet (apart from breastmilk) ⁵	 15. Milk feeding frequency for non-breastfed children: proportion of non-breastfed children 6- 23.9 months of age who receive at least two milk feedings⁸
8. Consumption of iron-rich or iron-fortified foods: proportion of children 6-23.9 months of age who receive an iron-rich or iron-fortified food that is specially designed for infants and young children, or that is fortified in the home	

Table 2. Set of infant and young child feeding indicators proposed by WHO.

I. Indicators 2-8, 10-12 and 14-15 are based on a 24-hour recall period. Indicators 1, 2, 7 and 8 are considered top priorities for reporting among the core indicators.

2. Can be disaggregated for ages 0-1, 2-3, 4-5 and 0-3 months.

3. The seven food groups used for tabulation of this indicator are: grains, roots and tubers; legumes and nuts; dairy products (milk, yogurt, cheese); flesh foods (meat, fish, poultry and liver/organ meats); eggs; vitamin A rich fruits and vegetables; other fruits and vegetables.

7. This is the only indicator that requires collection of data in children above 24 months; its calculation is explained in an annex to the WHO consensus document.

8. Infant formula, cow milk or other animal milk.

^{4.} Minimum is defined as: two times for breastfed infants 6-8.9 months; three times for breastfed children 9-23.9 months; four times for non-breastfed children 6-23.9 months.

^{5.} This composite indicators is the sum of two fractions: the proportion of breastfed children 6-23.9 months of age who had at least the minimum dietary diversity and the minimum meal frequency during the previous day, plus the proportion of non-breastfed children 6-23.9 months of age who received at least two milk feedings and had at least the minimum dietary diversity and the minimum meal frequency during the previous day.

^{6.} This indicator is the sum of exclusive breastfeeding under six months plus the proportion of children 6-23.9 months of age who received breastmilk as well as solid, semi-solid or soft foods during the previous day.

The current proposal from the EU Health Monitoring Programme includes the following indicators: 61

- breastfeeding and exclusive breastfeeding at 48 hours;
- breastfeeding and exclusive breastfeeding at 3 and 6 months;
- breastfeeding at 12 months.

These are also recommended by other EU projects (Perinatal, Child, and Public Health Nutrition projects). Having a short list of recommended indicators, however, does not constitute agreement for universal use of standard definitions and methods/timing of data collection. More work is needed to develop consensus and issue standard recommendations for data collection, keeping the WHO recommendations and proposals into account.

Monitoring and evaluation of breastfeeding standard practices in health and social service provision, the extent to which policies, laws and codes have been implemented, the range and effectiveness of CBSC activities, and the effectiveness and proliferation of training should also be an integral part of action plans. At least some universal criteria for best practice, such as those developed by WHO and UNICEF for the BFHI, should be used to ensure some comparability within and between countries.

6. RESEARCH

The development of the Blueprint for Action, and more precisely the review of interventions,³⁵ revealed the need for further research into several single and/or combined interventions to ascertain their effect on breastfeeding practices. In particular, a need was identified to explore the effect on breastfeeding rates and practices of commercial marketing of breastmilk substitutes, the impact of maternity protection legislation, the use of different CBSC approaches and interventions, as well as other public health initiatives not amenable to assessment by rigorous research methods (e.g. randomised controlled trials).⁶² Alternatively, randomisation can be applied to clusters and communities, rather than individuals; but this too may not be feasible. Other types of controlled study designs may need to be applied in these situations, for example, non-randomised controlled studies or historical before-and-after studies comparing geographical areas or population groups.^{63,64} The cost/benefit, cost/ effectiveness and feasibility of different interventions need further research also.

Good quality research methods for both quantitative and qualitative research should be employed, including:

- Consistency in the use of standard definitions of feeding categories (including recall periods) and of other variables;
- The use of valid criteria for recruitment of study subjects (inclusion and exclusion criteria; no self-selection);
- The use, when applicable, of an appropriate experimental design (randomised controlled trial and intention-to-treat analysis);
- The use of appropriate power and sample sizes compatible with the objectives of the research being undertaken (e.g. to detect statistical significance with narrow confidence intervals);
- Appropriate handling of confounders with proper factorial analysis (comprehensive baseline data);
- The use of appropriate qualitative research methods such as:⁶⁵
- Structured, semi structured and in-depth interviews;
- Focus groups and interviews with key informants;
- Observation of real or simulated practice, or response to different scenarios;
- Analysis of recorded speech (audio) or behaviour (video).

In implementing research, it is important to note that it is not possible or ethical to randomly assign mothers to breastfeed or not breastfeed. Assessing the effectiveness of breastfeeding support services, including mother-to-mother support, should be approached with caution, especially retrospectively, as users of these services are generally the groups in society most likely to breastfeed and are selfselecting. Prospective research in this area should also be approached with caution because of the myriad of confounding variables involved.

Ethical guidelines for research on breastfeeding/infant feeding by health authorities, health professional colleges, schools and professional associations should ensure freedom from all competing and commercial interests. The disclosure and handling of potential conflicts of interest of researchers is of paramount importance. Research in biomonitoring using breastmilk and the communication of results should not undermine the positive public health messages about breastfeeding. WHO has developed a special protocol containing prenatal breastfeeding information for mothers being enrolled in biomonitoring and examples of good communication.^p

VI. Operational tables

I. POLICY AND PLANNING, MANAGEMENT AND FINANCING

1.1 Policy

Reco	mmended objectives	Responsibility	Outputs and outcomes
1.1.1.	To develop a comprehensive national policy based on the Global Strategy and integrate it into overall health policies	Relevant ministries, national breastfeeding and/ or infant and young child feeding committees	Policy drafted, finalised, published and disseminated
1.1.2.	To integrate into the national policy specific policies for socially disadvantaged groups and children in exceptionally difficult circumstances to reduce inequalities	Relevant ministries, national breastfeeding committees	Policy drafted, finalised, published and disseminated
1.1.3.	To encourage professional associations to issue recommendations and practice guidelines based on the national policies and standard recommendations, and ensure their members follow these.	Relevant ministries, professional associations	Recommendations drafted, finalised, published and disseminated

1.2. Planning

Reco	ommended objectives	Responsibility	Outputs and outcomes
1.2.1.	To set priorities, objectives and targets based on the comprehensive national policy	Relevant ministries, breastfeeding committees	Priorities, objectives and targets set
1.2.2.	To develop a long term (5-10 years) strategic plan within the national health plan and to re- plan after evaluation	Relevant ministries, breastfeeding committees	Strategic plan developed, agreed and published
1.2.3.	To develop short term (1-2 years) national/ regional operational plans and to re-plan based on monitoring	Relevant ministries, regional health authorities	Operational plans developed, agreed and published
1.2.4.	To coordinate breastfeeding initiatives with other public health and health promotion plans and activities	Relevant ministries, regional health authorities	Intra- and inter-sectoral coordinating committees established; other public health plans and activities reflect breastfeeding policies
1.2.5.	To set up a monitoring system for breastfeeding rates based on universally agreed standard definitions and methods	Relevant ministries and authorities, national statistical bodies, breastfeeding committees	Monitoring system set up, data gathered and regularly analysed
1.2.6.	To gather, in addition to breastfeeding rates, linked information on maternal age, education and socio-economic status to help identify the extent and nature of inequalities in prevalence of breastfeeding	Relevant ministries and authorities, national statistical bodies	Other relevant variables incorporated into data collection systems
1.2.7.	To publish and disseminate the results of monitoring, and use them to monitor and inform the future planning of breastfeeding initiatives	Relevant ministries and authorities, national statistical bodies, breastfeeding committees	Results published, disseminated and used for re-planning, including commitment to address inequalities identified

1.3. Management

Reco	mmended objectives	Responsibility	Outputs and outcomes
1.3.1.	To designate a suitably qualified national/ regional coordinator with clear terms of reference related to policies and plans	Relevant ministries, regional health authorities	National/regional coordinators designated/ appointed
1.3.2.	To establish a national/regional intersectoral breastfeeding committee to advise/support the national/regional coordinator	Relevant ministries, regional health authorities	National/regional committees established
1.3.3.	To ensure continuity of the national/ regional coordinator's and committee's activities	Relevant ministries, regional health authorities	Breastfeeding coordinators and committees have jointly pledged to implement the action plan
1.3.4.	To regularly monitor progress and periodically evaluate results of the national/regional plan	Breastfeeding coordinators and committees	Regular progress reports and periodic evaluation reports produced

1.4. Financing

Recommended objectives	Responsibility	Outputs and outcomes
I.4.1. To assign adequate human and financial resources for the protection, promotion and support of breastfeeding	Government, relevant ministries and authorities	Realistic year-on-year budget allocated
1.4.2. To ensure that policy development, planning, implementation, monitoring and evaluation of activities are carried out independent of funding from manufacturers and distributors of products under the scope of the International Code	Government, relevant ministries and health authorities, local health providers	Sources of funds clearly and transparently indicated

2. COMMUNICATION FOR BEHAVIOUR AND SOCIAL CHANGE

2.1 CBSC for individual women and their families

Recommended objectives	Responsibility	Outputs and outcomes
2.1.1. To provide expectant and new parents with individual face-to-face counselling by appropriately trained health workers, peer caounsellors and mother-to-mother support groups	Relevant health authorities, health workers, peer counsellors, mother-to-mother support groups	Audit of parents' breastfeeding knowledge/skill and of how this information is conveyed
2.1.2. To ensure that all CBSC materials produced and distributed by health authorities contain clear, accurate and coherent information, are consistent with national and regional policies and recommendations, and are used to support face-to-face interactions	Relevant health authorities, breastfeeding coordinators and committees, health workers, peer counsellors, mother-to-mother support groups	Materials available meet the criteria of this objective; audit of CBSC materials and one-to-one breastfeeding communication procedures is carried out
2.1.3. To include communication models to protect breastfeeding in CBSC materials on the use of breastmilk as an indicator of environmental contamination (biomonitoring) ^q	Relevant health authorities, breastfeeding coordinators and committees, health workers, peer counsellors, mother-to- mother support groups	Materials available meet the criteria of this objective
2.1.4. To identify and actively address the particular information and skill needs of primiparae, immigrants, adolescents, single mothers, less educated women and others in society that are currently least likely to breastfeed, including mothers with previous difficult and unsuccessful breastfeeding experience	Relevant health authorities, breastfeeding coordinators and committees, health workers, peer counsellors, mother-to- mother support groups	CBSC services and materials produced meet high quality standards and are sensitive to the particular needs of the client groups
2.1.5. To identify and address the information needs of other family and kinship members, e.g. mother's partner/infant's father, infant's grand-parents, siblings, etc.	Relevant health authorities, breastfeeding coordinators and committees, health workers, peer counsellors, mother-to- mother support groups	Materials and supports developed/audited for these 'significant others'
2.1.6. To ensure that there is no advertising or other form of promotion to the general public of products under the scope of the International Code, including the distribution of information materials produced/sponsored by these product companies	Relevant health authorities, breastfeeding coordinators and committees	No advertising information or marketing materials produced or sponsored by companies manufacturing or selling these products are featured in the media or distributed to the general public
2.1.7. To regularly monitor and evaluate the coverage, standard and effectiveness of CBSC materials and activities	Relevant health authorities, breastfeeding coordinators and committees	Comprehensive coverage of high quality and regularly reviewed CBSC materials distributed to relevant health workers and users of maternity and child health services

 ${\tt q} \ {\tt see for \ example: http://www.who.int/foodsafety/chem/POPprotocol.pdf} \\$

2.2. CBSC for communities

Reco	mmended objectives	Responsibility	Outputs and outcomes
2.2.1.	To develop and disseminate CBSC packs that are consistent with national policies and recommendations, for use in health and social service facilities, in all levels of schools, with infant and child care provider groups, with policy and decision makers, and in the media; the information should be free-of- charge at the point of delivery	Relevant health, social and educational authorities, breastfeeding coordinators and committees, professional associations, NGOs, mother-to-mother/peer groups	CBSC packs developed and distributed; the effectiveness of distribution systems for CBSC packs regularly audited
2.2.2.	To present exclusive breastfeeding for six months and continued breastfeeding up to two years and beyond as the normal way to feed and nurture infants and young children in all written and visual materials	All multi-media organisations and commissioning authorities with responsibility for content of books, programmes, etc.	Information outlining their responsibility disseminated to the multi-media organisations; monitoring measures in place
2.2.3.	To use the international, national and local breastfeeding awareness weeks as an opportunity to stimulate public debate in different settings and media and to disseminate important information	Breastfeeding coordinators and committees, all relevant stakeholders	Media campaigns organised marking these and activities published.
2.2.4.	To monitor, inform and use all organs of the media to promote and support breastfeeding and to ensure that it is at all times portrayed as normal and desirable	Relevant health, social and educational authorities, breastfeeding coordinators and committees	Multi-media organisations provided with information and encouraged to promote breastfeeding as normal, natural and desirable. Media portrayals of breastfeeding audited and feedback provided.
2.2.5.	To monitor breastfeeding knowledge, attitudes and behaviour at societal level so as to take a more informed approach to effectively promoting, supporting and protecting it	Relevant health, social and educational authorities	Surveys, undertaken and results published and acted on.

3. TRAINING

3.1. Pre-service training

Recommended objectives	Responsibility	Outputs and outcomes
3.1.1. To develop, or review if existing, a minimum (contents, methods, time) standard for pre- and post-graduate curricula and competency on breastfeeding and lactation management for relevant health workers, including pharmacists	Deans of relevant health faculties, professional competency authorities, national breastfeeding committees	Curricula and competency standards developed/ updated and implemented
3.1.2. To develop, or review if existing, course textbooks and training materials in line with the updated standard curricula and recommended policies and practices	Deans and teachers of relevant health faculties, professional associations	Textbooks and training materials developed or updated, and in use

3.2. In-service training

Recommended objectives	Responsibility	Outputs and outcomes
3.2.1. To offer continuing interdisciplinary educa- tion based on WHO/UNICEF guidelines or other evidence-based courses on breast- feeding and lactation management, as part of induction and in-service education for all relevant health care staff, with particular emphasis on staff in frontline maternity and child care areas	Continuing Medical Education authorities, maternity and child health service provider institutions, health schools, in-service practice development coordinators, professional associations	In-service practical training provided for all relevant health workers and up- dates offered on a regular basis, based on recognised guidelines and courses
3.2.2. To develop, or review if existing, training materials to be used for such interdiscipli- nary continuing education, ensuring that materials and courses are not influenced by manufacturers and distributors of products under the scope of the International Code	Continuing Medical Education authorities, in-service practice development coordinators, health schools, breastfeeding committees, professional associations	Materials developed and reviewed; protocols in place to monitor and ensure that no conflicts of interest exist in the content of courses and materials
3.2.3. To encourage relevant health care workers to attend advanced lactation management accredited courses and to acquire the IBCLC or equivalent certification shown to meet best practice criteria for competence	Continuing Medical Education authorities, health service employers, IBLCE, professional associations	The ratio of certified practising lactation consultants to births per year is increasing
3.2.4. To encourage e-networking amongst breastfeeding specialists in order to increase knowledge and skills	Professional associations, public interest NGOs	Mailing lists, websites and discussion groups developed and activated
3.2.5. To monitor the coverage and effectiveness of in-service training	Continuing Medical Education authorities, breastfeeding committees, professional associations	Proficiency, competency and training coverage assessed

4. **PROTECTION, PROMOTION AND SUPPORT**

4.1. Global Strategy for Infant and Young Child Feeding

Recommended objectives	Responsibility	Outputs and outcomes
4.1.1. To implement policies and plans based on the Global Strategy and WHO/ EURO Action Plans	Ministry of Health and other relevant ministries	Policies and plans developed and implemented
4.1.2. To disseminate breastfeeding policies and plans to all health professional groups, relevant academic health professional colleges offering under- graduate and post-graduate training, NGOs and the general public	Health service providers, Ministry of Health and other relevant ministries	Health workers and the general public have knowledge of the breastfeeding policy/action plan
4.1.3. To regularly monitor progress and periodically evaluate results of national/regional policies and plans	Health service providers, Ministry of Health and other relevant ministries	Regular progress reports and periodic evaluation reports produced

4.2. The International Code

Rec	commended Objectives	Responsibility	Outputs and outcomes
4.2.1.	To develop EU regulations on the marketing of breastmilk substitutes which would include all the provisions and products under the scope of the International Code as a minimum requirement	European Commission, national governments	Regulations drafted and accepted by member states
4.2.2.	To ensure that the International Code is reflected in the EU position at meetings of Codex Alimentarius	European Commission, national governments, food safety and food standards agencies	Codex Alimentarius reports reflect this position
4.2.3.	To develop national legislation based on the International Code, including mechanisms for enforcement and prosecution of violations, and a monitoring system that is independent of commercial vested interests	National governments, breastfeeding committees, food standards agencies, advertising standards authorities, consumers' associations	National laws updated, com- pliance procedures in place in accordance with all the provisions in the International Code
4.2.4.	To encourage the full implementation of the International Code even when EU regulations do not require this of member states	National and local governments, breastfeeding committees, NGOs	National and local compliance procedures in place in accord- ance with all the provisions in the International Code
4.2.5.	To inform pre- and post-graduate health professionals and health service providers, including pharmacists, about their responsibilities under the International Code	University schools of health and social sciences, post-graduate education providers, Continuing Medical Education authorities, relevant health authorities	Information provided
4.2.6.	To develop code of ethics covering the criteria for the acceptance of individual and institutional sponsorship for courses, educational materials, research, conferences and other activities and events, to avoid conflicts of interest that are known to adversely affect breastfeeding	Professional associations, academic institutions and service providers	Criteria and guidelines devel- oped, published, implemented
4.2.7.	To disseminate information to the public on the principles, aims and provisions of the International Code and on procedures for monitoring compliance and censuring violations	National and regional governments, NGOs, consumers' associations	Information disseminated to public and to body responsible for monitoring
4.2.8.	To phase out the distribution of free formula to low income families, where this is still in place, and to replace it with incentives and initiatives to promote and support breastfeeding within families living in poverty or otherwise marginalized	National and regional governments, social support agencies	Free formula to low income families discontinued and replaced by incentives and initiatives aimed at increasing breastfeeding rates for these families
4.2.9.	To set up a monitoring system, independent of commercial interests, with responsibility for checking compliance with the International Code, investigating and if necessary prosecuting breaches, as well as producing information for the general public and the relevant authorities on any infringements that have taken place in the relevant jurisdiction	Relevant ministries and health authorities, breastfeeding coordinators and committees, consumers' associations	Monitoring procedures in place and operative; regular publication and dissemination of the outcome of infringe- ments of the International Code occurring.

4.3. Legislation for working mothers

Reco	ommended Objectives	Responsibility	Outputs and outcomes
4.3.1.	To extend national maternity protection legislation in order to support mothers to achieve breastfeeding best practice recommendations	National and regional governments	ILO Convention 183 ratified, legislation upgraded
4.3.2.	To ensure that sufficient legislative supports are in place to enable working mothers to exclusively breastfeed their infants for six months and to continue thereafter in line with best evidence-based recommendations	National and regional governments	Effective legislative supports enacted, financial support approved
4.3.3.	To extend maternity protection legislative provisions to women who are not currently entitled to these: e.g. women with short term contracts, casual and part-time workers, students and immigrants	National and regional governments	Legislation extended, equity for all working mothers
4.3.4.	To ensure that employers, health workers and the public are fully informed about maternity protection and health and safety at work legislation as related to pregnant and breastfeeding women	National and regional governments, human resources departments, health promotion agencies, employer organizations, trade unions	Increased awareness of existing provisions on maternity protection
4.3.5.	To inform employers of the benefits to them and their breastfeeding employees of facilitating breastfeeding following return to the workplace, and the facilities necessary to ensure that this is possible (flexible hours, time-off, and facilities for expressing and storing breastmilk)	Relevant ministries, health and social authorities, human resources departments, health promotion agencies, employer organizations, trade unions	Employers informed of benefits and offering appropriate workplace supports
4.3.6.	To monitor the implementation, in both public and private sectors, of national policies and legislation, including maternity protection laws, relating to breastfeeding	National and regional governments, employer organizations, trade unions, public interest NGOs, professional associations	Monitoring carried out, regular publication of findings

4.4. Baby Friendly Hospital Initiative

Recommended Objectives	Responsibility	Outputs and outcomes
4.4.1. To ensure that government, health authorities, professional associations and relevant NGOs closely collaborate with UNICEF and WHO to implement the BFHI as a standard for best prac- tice, and that all maternity and child care institu- tions and providers pursue the goal of achieving and maintaining the 'Baby Friendly' designation, including compliance with the International Code	National and regional governments, relevant health authorities, clinical guideline agencies, health care commissions, professional associations, NGOs, breastfeeding committees, maternity and child care service providers	BFHI committees and coordinators established and BFHI universally recognised as standard of excellence in the provision of breastfeeding services
4.4.2. To ensure adequate resources (funds, personnel/ time) and technical support for training, change of practices, assessment and re-assessment of hospitals based on compliance with the BFHI	National and regional governments, relevant health authorities, quality assurance committees	Adequate budget/personnel allocation to achieve the standard of care based on BFHI for all expectant parents and breastfeeding mothers
4.4.3. To ensure that maternity hospitals not currently participating in the BFHI are implementing the practices described in the 10 steps as these represent best evidence-based practice	Relevant health authorities; quality assurance and BFHI committees	All hospitals/units using best practice standards
4.4.4. To incorporate the achievement of all the BFHI criteria into the standards for quality accredita- tion of maternity and paediatric health service providers.	Relevant health authorities; quality assurance, accreditation and BFHI committees	Maternity and paediatric health service provider accreditation standards include all the BFHI criteria
4.4.5. To develop a systematic approach to conveying breastfeeding information during antenatal care, consistent with relevant steps of the BFHI	Relevant health authorities, health service providers, health workers	Guidelines for antenatal care produced
4.4.6. To involve fathers and families to ensure appro- priate support for mothers on discharge home	Health service providers, health workers	Fathers and families involved
4.4.7. To implement step 10 by improving cooperation between hospitals and other health and social care facilities and mother-to-mother groups so as to ensure the provision of optimum lactation support and counselling, especially during the crucial weeks after birth	Relevant health and social authorities; quality assurance and BFHI committees, peer counsellors, mother-to- mother support groups, voluntary breastfeeding support organisations, NGOs	Widespread implementation of Step 10 of the BFHI
4.4.8. To ensure that adequate resources and techni- cal support for training and necessary changes in practice are provided so that community health and social services for women, infants and children effectively promote and support breastfeeding	Relevant health and social authorities, professional associations, educational institutions	Public and private health and social service providers promote and support breastfeeding in line with breastfeeding policies
4.4.9. To develop and implement the Baby Friendly Initiative for settings other than maternity hospi- tals, to include community health and allied social care settings, paediatric hospitals, pharmacies and workplaces	Relevant health and social authorities; quality assurance and BFHI committees, NGOs	Models of care based on the BFHI developed and implemented in other health and related service areas
4.4.10. To draw up protocols and instigate procedures for the regular assessment of hospital and primary health care practices, based on standard best prac- tice criteria as developed for the BFHI by WHO/ UNICEF and by national/regional committees	Relevant ministries and authorities, BFHI and quality assurance committees, NGOs	Regular assessment protocols and procedures in place for all maternity, child health and primary health care facilities

Rec	commended Objectives	Responsibility	Outputs and outcomes
4.5.1	To ensure that the skilled breastfeeding support provided by health and allied social care workers and mother-to-mother volun- teers is confidence-building and empowering for mothers and their families	Relevant health and social authorities, agencies, voluntary organizations and health workers	Audit the number of staff and volunteers who are competent to effectively support breastfeeding and address deficits identified
4.5.2	To ensure that mothers with particular breastfeeding difficulties, including those with difficulties formula feeding their infants and children, are individually assisted by skilled counsellors	Relevant health authorities, health service providers, health workers	Breastfeeding coordinators and specialists, such as IBCLCs, are trained and employed to provide this service and teach other staff in the effective management of breastfeeding problems
4.5.3	To ensure that all mothers have free access to infant and young child feeding support services, including the services of appropri- ately qualified lactation consultants, or other equally competent health care staff, if prob- lems arise	Relevant health and social authorities, agencies and organizations, health insurance providers	National health systems and/or voluntary health insurance com- panies cover the cost of skilled breastfeeding support and lacta- tion consultant services
4.5.4	To provide mothers of ill or preterm infants with the support necessary to ensure that they are able to maintain their lactation and express sufficient breastmilk for their babies needs (this support should include free travel and accommodation so that they can be with or near their babies as much as possible), or to provide free safe donor breastmilk	Relevant health and social authorities, agencies and organizations	Assistance and support pro- vided, at no extra cost to the mother
4.5.5	National and regional breastfeeding centres of excellence to be established as resource cen- tres for health workers and mothers; these to include access to relevant journals, textbooks and materials, including free access to web- based peer reviewed expert information	National and regional health authorities, breastfeeding committees	Centres established, access information disseminated to all relevant groups
4.5.6	To ensure that women who stop breastfeed- ing before they had planned to are facilitated to examine why this happened in order to reduce feelings of loss or failure they may be experiencing, and help them attain longer breastfeeding with a subsequent baby	Relevant health authorities, health service providers, health workers	Staff and volunteers are aware and competent to help a mother who may need to debrief after ceasing breast- feeding earlier than planned.
4.5.7	To put in place routine patient/client feed- back through audit and satisfaction surveys to determine the quality of the breastfeed- ing information and support provided by maternity and paediatric service providers and primary health care practices ^r	Directors of hospitals and primary health care practices, quality assur- ance committees, breast- feeding coordinators and lactation specialists	Routine patient feedback procedures instigated and protocols put in place for addressing any sub-optimal practices discovered

^r Examples in Annex 3 of the revised BFHI package (see www.unicef.org/nutrition/index_24850.html or www.who.int/nutrition/topics/bfhi/en/index.html)

Reco	ommended Objectives	Responsibility	Outputs and outcomes
4.6.1	To encourage the establishment and increase the coverage of support services provided by trained peer counsellors and mother-to-mother support groups, particularly in lower socio-economic status and marginalised communities, where women are less likely to breastfeed	Relevant health authorities, health promotion and public health commissioners, peer counsellors, mother-to- mother support groups, voluntary breastfeeding support organisations	Training/establishment of peer counsellor and mother-to-mother support groups in areas where they are most needed
4.6.2	To develop or review/update curricula (contents, methods, materials, time) for peer counsellor and mother-to-mother support training	Peer counsellors, mother- to-mother support groups, voluntary breastfeeding support organisations	Curricula and competency standards updated/reviewed or developed
4.6.3	To strengthen the cooperation and communication between health workers based in different health facilities and trained peer counsellors and mother-to- mother support groups	Relevant health authorities, health workers, peer counsellors, mother-to- mother support groups, voluntary breastfeeding support organisations	Procedures in place to facilitate effective use of statutory and voluntary breastfeeding expertise

4.6. Support by trained peer counsellors and mother-to-mother support groups

4.7. Support in the family, community and workplace

Reco	ommended Objectives	Responsibility	Outputs and outcomes
4.7.1	To give appropriate information and support to breastfeeding mothers, their partners and families, including contact details for recognised breastfeeding support networks, both statutory and voluntary	Relevant health and social authorities, health workers, peer counsellors, mother-to-mother support groups	Breastfeeding mothers and their partners routinely given this information and support
4.7.2	To encourage family support through public education and local projects, and through community programmes based on collaboration between voluntary and statutory community services providers	Relevant health and social authorities, health workers, peer counsellors, mother-to-mother support groups	Local and community inter- sectoral projects established and evaluated
4.7.3	To identify and address the particular support needs of primiparae, immigrants, adolescents, single mothers, less educated women and others in society that are currently least likely to breastfeed, including mothers with previous difficult and/or unsuccessful breastfeeding experiences, and mothers of formula fed infants and young children	Relevant health and social authorities, health workers, research institutions, peer counsellors, mother-to- mother support groups	The information and support needs of these groups are identified and addressed appropriately
4.7.4	To encourage breastfeeding friendly policies/facilities in workplaces and public service/amenity areas and to protect the right of women to continue breastfeeding for as long as they wish through enacting appropriate policies and legislation	National and regional governments, relevant health and social authorities, human resources departments	Widespread breastfeeding friendly policies/facilities adopted and enacted

5. MONITORING

The items of the operational tables for monitoring have been incorporated into the operational tables of the other sections and can be found under various headings.

6. **RESEARCH**

The items of the operational tables for monitoring have been incorporated into the operational tables of the other sections and can be found under various headings.

Obje	ectives	Responsibility	Outputs and outcomes
6.1.1	To foster and support research on breastfeeding based on agreed priorities and agenda, using agreed definitions of breastfeeding, and free from competing and commercial interests	European Commission, governments, ministries of health, research institutions, breastfeeding committees	Annual budget allocation for breastfeeding research. Research projects published and disseminated and an electronic database of breastfeeding research maintained. Gaps in research knowledge also identified.
6.1.2	To support and ensure intensive exchange of expertise in breastfeeding research among research institutions in Member States	European Commission, governments, research institutions, breastfeeding committees, professional associations	Increase in number of collaborative projects and publications

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Annex I. The Global Strategy for Infant and Young Child Feeding

WHO and UNICEF jointly developed the Global Strategy in 2002, incorporating the latest research knowledge, with the aim of rekindling world interest in the urgent need to protect, promote and support breastfeeding and improve, through optimal feeding, the nutritional status, growth and development, health, and consequently the survival of infants and young children.

The development of the Global Strategy during a two-year comprehensive process was guided by two principles: it should be grounded on the best available scientific and epidemiological evidence, and it should be as participatory as possible. From the beginning it was agreed that the Global Strategy should endorse and build on past and continuing achievements, particularly the BFHI (1991), the International Code of Marketing of Breastmilk Substitutes (1981) and the Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding (1990).

The Global Strategy is intended as a guide for action; its specific objectives are: to raise awareness of the main problems affecting infant and young child feeding; to identify approaches to their solution and provide a framework of essential interventions; to increase the commitment of governments, international organizations and other concerned parties for optimal feeding practices for infants and young children; to create an environment that will enable mothers, families and other caregivers in all circumstances to make and implement informed choices about optimal feeding practices for infants and young children.

The Global Strategy needs to be translated into action. There is convincing evidence from around the world that governments, with the support of the international community and other concerned parties, are beginning to take seriously their commitments to protect and promote the health and nutritional well-being of infants, young children, and pregnant and lactating women.

The first four of the nine operational targets of the Global Strategy are taken from the Innocenti Declaration (Annex 3). The five additional targets are:

- 5. Develop, implement, monitor and evaluate a comprehensive policy on infant and young child feeding, in the context of national policies and programmes for nutrition, child and reproductive health, and poverty reduction.
- 6. Ensure that the health and other relevant sectors protect, promote and support exclusive breastfeeding for six months and continued breastfeeding up to two years of age or beyond, while providing women access to the support they require in the family, community and workplace to achieve this goal.
- 7. Promote timely, adequate, safe and appropriate complementary feeding with continued breastfeeding.
- 8. Provide guidance on feeding infants and young children in exceptionally difficult circumstances, and on the related support required by mothers, families and other caregivers.
- 9. Consider what new legislation or other suitable measures may be required, as part of a comprehensive policy on infant and young child feeding, to give effect to the principles and aim of the International Code of Marketing of Breastmilk Substitutes and to subsequent relevant Health Assembly resolutions.

Annex 2. The International Code of Marketing of Breastmilk Substitutes

The International Code covers breastmilk substitutes, including "infant formula, other milk products, foods and beverages for use as a partial or total replacement for breastmilk, feeding bottles and teats", and was adopted in 1981 at the WHA by the majority of Member States to stem the aggressive marketing of formula milk and the resultant rise in infant mortality. After the adoption of the International Code, the infant formula companies developed and began marketing follow-up formulae to ensure the continuing visibility of their brand names and products. In response, a 1986 WHA Resolution clarified that there is no clinical need for these products and that artificially fed infants should be fed standard infant formula to 12 months and thereafter should receive full fat unmodified cow's milk as well as nutritious family foods.

Subsequent WHA Resolutions have updated and clarified the International Code as necessary, to take account of new scientific knowledge and commercial product marketing trends. These Resolutions have the same status as the International Code, as reaffirmed by a technical endorsement from the WHO secretariat.

The main provisions of the International Code and subsequent relevant WHA Resolutions are:

- 1. Governments have the responsibility to provide information on infant feeding. Donations of informational materials by manufacturers or distributors should only be made at the request and with the written approval of the appropriate government authority.
- 2. No advertising of breastmilk substitutes to the public.
- 3. No direct or indirect free samples or gifts to mothers or their relatives.
- 4. No company sales representatives to contact mothers directly or indirectly.
- 5. No gifts or personal samples to health workers. Samples provided are to be for professional evaluation or research at institutional level. Health workers should not give samples to pregnant women or mothers of infants and young children.
- 6. Information to health workers should be scientific and factual.
- 7. Financial support to health professionals should not create conflicts of interest.
- 8. All information to mothers should include the benefits of breastfeeding and the costs and hazards of artificial feeding.
- 9. No promotion of products covered by the International Code in health care facilities including no free supplies.
- 10. No words like "humanized", "maternalized", or similar terms, pictures and text idealising artificial feeding on labels.
- 11. Nutritional and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation.

Successful implementation of the International Code depends on countries incorporating and enforcing its provisions into their national/regional legislation. The International Code, however, states that irrespective of such incorporation, industries should monitor their own practice and conform to the principles and aims of the International Code itself. Although sponsorship of health programmes and health professionals, including training, is not prohibited by the International Code, the 1996 and 2005 WHA Resolutions cautioned against conflicts of interest. Health professionals may feel they are immune to commercial promotional activities. Social science studies have concluded otherwise: even "small gifts" have an effect.

The International Code does not prohibit the sale of breastmilk substitutes but regulates their marketing. Advertisement and promotion of a product for sale may be a widely accepted practice in the commercial world but the marketing of breastmilk substitutes adversely affects the up-take

and duration of breastfeeding and cannot be treated in the same way as other commercial products. The low rates of breastfeeding worldwide are a major public health concern and efforts to address this situation should not have to compete with commercial enterprises with increasingly more sophisticated marketing tools and massive budgets.

As health advocates, apart from urging the government to take action to address low breastfeeding rates, health workers have responsibilities under the provisions of the International Code. They can ensure that health care facilities are not used for product promotion. They can monitor and report violations to the relevant statutory bodies, as recommended by the WHA. At the very least, health workers should familiarise themselves with the spirit and provisions of the International Code and subsequent relevant WHA Resolutions so as not to inadvertently facilitate violations, to the detriment of the community health.

The European Union first transposed the International Code into a Directive of the European Commission in 1991 (Directive 91/321/EEC). This Directive was far from encompassing the International Code in its integrity insofar as it applied only to infant and follow-on formulae and limited their marketing only to infants under four months of age. In December 2006 the European Commission issued Directive 2006/141/EC to update and replace the 1991 Directive. The 2006/141/ EC Directive represents very little improvement over the 91/321/EEC Directive: it just extends the marketing limitations to infants up to six months. Almost at the same time, the European Commission issued Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children. Article 8.1.a of this Directive says that the label of these products must bear a statement as to the appropriate age from which the product may be used; it adds that "the stated age shall not be less than four months", thus contradicting many national recommendations for exclusive breastfeeding up to six months. The Directives of the European Commission are to be transposed into national laws or regulations in all Member States.

Annex 3. The Innocenti Declaration

The 1990 Innocenti Declaration on Protection, Promotion and Support of Breastfeeding

On 1st August 1990 in Florence, Italy, representatives from 30 national governments adopted the Innocenti Declaration, a document that established new strategic objectives to more effectively protect, promote and support breastfeeding. The four operational targets of the 1990 Innocenti Declaration were:

- I. to appoint a national breastfeeding coordinator and establish a multisectoral national breastfeeding committee;
- 2. to ensure that every facility providing maternity services fully practices all the 10 Steps to Successful Breastfeeding;
- 3. to give effect to the principles and aim of the International Code in their entirety; and
- 4. to enact legislation protecting the breastfeeding rights of working women and establish means for its enforcement.

The 2005 Innocenti Declaration on Infant and Young Child Feeding

On 22nd November 2005 in Florence, Italy, an anniversary celebration was held entitled "Celebrating Innocenti 1990-2005: Achievements, Challenges and Future Imperatives". Participating delegates adopted the Innocenti Declaration 2005. This consists of several urgent and necessary actions to ensure the best start in life for children, the realisation of the human rights for women and children, and the achievement of the MDG by 2015. The Declaration identifies roles and responsibilities of key players and emphasizes that these responsibilities need to be met to achieve an environment that enables mothers, families and other caregivers to make informed decisions about optimal infant feeding. This call for required actions includes:

All parties:

- I. Empower women;
- 2. Support breastfeeding as the norm;
- 3. Highlight the risks of artificial feeding;
- 4. Ensure the health and nutritional status of women throughout their life;
- 5. Protect breastfeeding in emergencies, including uninterrupted breastfeeding, appropriate complementary feeding, and avoid distribution of breastmilk substitutes;
- 6. Implement the WHO HIV and Infant Feeding Guidelines.

All governments:

- 7. Establish or strengthen national infant and young child feeding authorities, coordinating committees and groups free from commercial influence and conflicts of interest;
- 8. Revitalise the BFHI, expanding the Initiative's application to include maternity, neonatal and child health services and community based support;
- 9. Implement all provisions of the International Code in their entirety as a minimum requirement, and establish enforcement mechanisms to prevent and/or address non-compliance;
- 10. Adopt maternity protection legislation that facilitates six months of exclusive breastfeeding;
- 11. Ensure that appropriate guidelines and skill acquisition are included in both pre-service and in-service training of all health care staff to provide a high standard of breastfeeding and complementary feeding management and counselling;
- 12. Ensure that all mothers are aware of their rights and have access to support, information and counselling;
- 13. Establish monitoring systems for infant and young child feeding patterns;

- 14. Encourage the media to support breastfeeding as the norm, to provide positive images of optimal infant and young child feeding, and to participate in WBW activities;
- 15. Take measures to protect populations, especially pregnant and breastfeeding mothers, from environmental contaminants and chemical residues;
- 16. Identify and allocate resources to implement actions called for in the Global Strategy;
- 17. Monitor progress and report periodically.

All manufacturers and distributors of products within the scope of the International Code:

- Ensure full compliance with all provisions of the International Code and subsequent relevant WHA Resolutions in all countries;
- 19. Ensure that all processed foods for infants and young children meet applicable Codex Alimentarius standards.

Multilateral and bilateral organisations and international financial institutions:

- 20. Recognise that optimal breastfeeding and complementary feeding are essential to achieving the long-term physical, intellectual and emotional health of all populations and that inappropriate feeding practices and their consequences are major obstacles to poverty reduction and sustainable socio-economic development;
- 21. Identify and allocate sufficient human and financial resources to support governments in formulating, implementing, monitoring and evaluating their policies and programmes on optimal infant and young child feeding and BFHI;
- 22. Increase technical guidance and support for national capacity building in all areas set forth in the Global Strategy;
- 23. Support operational research;
- 24. Encourage the inclusion of programmes to improve breastfeeding and complementary feeding in poverty-reduction strategies and health sector development plans.

Public interest non-governmental organisations:

- 25. Give greater priority to protecting, promoting and supporting optimal feeding practices, including training of health and community workers, and increase effectiveness through cooperation and mutual support;
- 26. Draw attention to activities which are incompatible with the International Code's principles so that violations can be effectively addressed in accordance with national legislation and regulations.
- 27. Any partnerships be governed by guidelines which ensure that they are appropriate and focus on clearly identified actions, in keeping with the principles for avoiding conflicts of interest and undue commercial influence.

The Innocenti Declaration 2005 was endorsed by the 2006 Annual Session of UN Standing Committee on Nutrition, and the WHA 2006 urged Member States to support actions contained in the Call for Action (WHA resolution 59.21).

The BFHI, launched in 1991, is the UNICEF/WHO's primary intervention strategy for strengthening the capacity of national, regional and local health systems to protect and support breastfeeding. The BFHI has thus been incorporated into best practice initiatives in maternity services worldwide and has been shown to have achieved significant improvements in breastfeeding rates and practices wherever it is applied. WHO/UNICEF accredits hospitals with a "Baby Friendly" quality standard designation when they have made the institutional and practice changes necessary to meet the Initiative's stringent assessment criteria. A BFH is a health care facility where the WHO/UNICEF 10 Steps to Successful Breastfeeding are the standard for maternal and child care with the aim of effectively protecting, promoting and supporting exclusive breastfeeding from birth.

The original BFHI guidelines were developed in 1992 by UNICEF and WellStart International. The guidelines were revised in 2006. The following are the revised 10 Steps to Successful Breastfeeding:

- I. Have a written breastfeeding policy that is routinely communicated to all health care staff.
- 2. Train all health care staff in skills necessary to implement this policy.
- 3. Inform all pregnant women about the benefits and management of breastfeeding.
- 4. Help mothers initiate breastfeeding within a half-hour of birth.
- 5. Show mothers how to breastfeed, and how to maintain lactation even if they should be separated from their infants.
- 6. Give newborn infants no food or drink other than breastmilk unless medically indicated.
- 7. Practise rooming in allow mothers and infants to remain together 24 hours a day.
- 8. Encourage breastfeeding on demand.
- 9. Give no artificial teats or pacifiers (dummies, soothers) to breastfeeding infants.
- 10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

The revised BFHI package, available from UNICEF,^s includes:

- Background documents and a guide for implementation;
- A course for decision-makers on strengthening and sustaining the BFHI;
- A 20-hour course for maternity staff on Breastfeeding Promotion and Support in a BFH including a training module on the impact of birthing practices on breastfeeding and a module for HIV prevalent regions;
- A tool for hospital self-appraisal and monitoring;
- Guidelines and tools for external assessment and reassessment (only available for assessors).

In many countries, the BFHI has been complemented by initiatives aimed at protecting, promoting and supporting breastfeeding:

- before and after childbirth through primary health care and community services;
- among sick and preterm infants in hospitals.

There are neither universal criteria nor guidelines for the BFCI, because each national project has been developed based on the local situation and organization of primary health care and community services.

Annex 5. The WHO/EURO food and nutrition policies and plans

WHO/EURO has already issued, after approval from all Member States, two Action Plans for Food and Nutrition Policy. The second was published in September 2007 and covers the period between 2007 and 2012. After recognizing that the Blueprint represents an important document that indicates strategic directions for action, this plan establishes health, nutrition, food safety and food security goals and objectives, and provides a coherent set of integrated actions, spanning different government sectors and involving public and private actors, for Member States to consider in their own national policies and plans. As far as infant and young child feeding is concerned, the plan recognizes that exclusive breastfeeding up to six months and the timely introduction of safe and appropriate complementary foods in addition to continued breastfeeding for up to two years can reduce the short- and long-term burden of ill health, and recommends to:

- Promote optimal foetal nutrition by ensuring good maternal nutrition from pre-conception, establishing support schemes for low socioeconomic groups and providing micronutrient supplementation as required;
 - Protect, promote and support breastfeeding by:
 - reviewing existing guidelines;
 - ensuring compliance with the criteria of the BFHI;
 - implementing and enforcing the International Code;
 - allowing adequate parental leave, breastfeeding breaks and flexibility to support working women during lactation and early childhood;
 - so that at least 50% of infants be exclusively breastfed for the first six months of life and continuously breastfed at least until 12 months;
- Take community-based initiatives to ensure adequate provision of complementary foods, sufficient micronutrient intake and proper nutritional care of infants and young children, particular those living in exceptionally difficult circumstances. When micronutrient fortification is used the impact and the potential risks should be monitored and conflicts of interests with the practice of exclusive breastfeeding should be avoided;
- Promote the development of pre-school and school nutrition and food safety policies, including improvement of curricula for education in nutrition, training of teachers, development of guidelines for school meals, and provision of healthy food options.

In addition, the plan recommends taking integrated action to address the determinants of poor and unhealthy nutrition.

Annex 6. The ILO Maternity Protection Convention 183

The Convention concerns the Revision of the Maternity Protection Convention of 1952. In order to further promote equality of all women in the workforce and the health and safety of the mother and child, and taking into account the circumstances of women workers and the need to provide protection for pregnancy, which is the shared responsibility of government and society, the Maternity Protection Convention 183 has been stipulated on 15th June 2000. The relevant points for Members that ratify the Convention, which is legally binding, are:

- this Convention applies to all employed women, including those in atypical forms of dependent work;
- each Member shall list the categories of workers thus excluded and the reasons for their exclusion;
- in its subsequent reports, the Members shall describe the measures taken with a view to progressively extending the provisions of the Convention to these categories.

Health protection:

• Each Member shall adopt appropriate measures to ensure that pregnant or breastfeeding women are not obliged to perform work which has been determined to be prejudicial to the health of the mother or the child.

Maternity leave

- On production of a medical certificate, stating the presumed date of childbirth, a woman to whom this Convention applies shall be entitled to a period of maternity leave of not less than 14 weeks.
- Each Member may subsequently deposit with the Director-General of the ILO a further declaration extending the period of maternity leave.
- With due regard to the protection of the health of the mother and that of the child, maternity leave shall include a period of six weeks' compulsory leave after childbirth.
- The prenatal portion of maternity leave shall be extended by any period elapsing between the presumed date of childbirth and the actual date of childbirth, without reduction in any compulsory portion of postnatal leave.

Benefits

- Cash benefits shall be provided to women on maternity leave.
- Cash benefits shall be at a level which ensures that the woman can maintain herself and her child in proper conditions of health and living standard.
- The amount of such benefits shall not be less than two-thirds of the woman's previous earnings.
- Where a woman does not meet the conditions to qualify for cash benefits she shall be entitled to adequate benefits out of social assistance funds.
- Medical benefits shall be provided for the woman and her child including prenatal, childbirth and postnatal care, as well as hospitalization care when necessary.
- In order to protect the situation of women in the labour market, benefits in respect of the leave shall be provided through compulsory social insurance or public funds.

Employment protection and non-discrimination

- It shall be unlawful for an employer to terminate the employment of a woman during her pregnancy or absence on leave or during a period following her return to work, except on grounds unrelated to the pregnancy or birth of the child and its consequences or nursing.
- A woman is guaranteed the right to return to the same position or an equivalent position paid

at the same rate at the end of her maternity leave.

Breastfeeding mothers

- A woman shall be provided with the right to one or more daily breaks or a daily reduction of hours of work to breastfeed her child.
- The period during which nursing breaks or the reduction of daily hours of work are allowed, their number, the duration of nursing breaks and the procedures for the reduction of daily hours of work shall be determined by national law and practice. These breaks or the reduction of daily hours of work shall be counted as working time and remunerated accordingly.

After the Convention 183, the ILO adopted the Recommendation 191, which gives guidelines and suggestions for the achievement of higher standards of maternity protection.

Annex 7. Template for an analysis of the situation

The following tables highlight the Blueprint for Action recommended objectives (left hand column) alongside the (country) progress (right hand column).

Count	ry: F	Period covered: from		to	Date:
Policy	ý	P	Policy		
1.1.1	National policy based on G	lobal Strategy			
1.1.2	Policy focusing on social dis	advantage			
1.1.3	Professional organisations p recommendations and prac				
Plann	ing	P	lanning		
1.2.1	Set priorities, objectives and	targets			
1.2.2	Long term planning, evaluati planning	on and re-			
1.2.3	Short term planning, monito planning	oring and re-			
1.2.4	Co-ordinate breastfeeding in other public health and hea activities				
1.2.5	Set up monitoring system v agreed definition and standa				
1.2.6	Gather other information of variables to help address in deprivation issues				
1.2.7	Publish and disseminate res future planning of breastfee				
Mana	gement	1	1 anageme	nt	
1.3.1	National co-ordinator				
1.3.2	National committee				
1.3.3	Continuity of co-ordinator	and committee			
1.3.4	Monitor and evaluate result plan	ts of national			
Finan	<u></u>	F	inance		

Finance	Finance
I.4.1 Adequate human and financial resources	
I.4.2 No formula company or distributor funding	

CBS	C (individuals)	CBSC (individuals)
2.1.1	Provision of face to face support by trained health workers including peer and group support	
2.1.2	Materials produced accurate and consistent with national policies	
2.1.3	Materials include the use of breastmilk as an indicator of environmental contamination	
2.1.4	Identify and address information and skills needs of women least likely to breastfeed (groups named)	
2.1.5	Identify and address needs of family and kinship members	
2.1.6	Prevent distribution of marketing materials on infant feeding from inappropriate sources	
2.1.7	Monitor and evaluate coverage, standard and effectiveness of CBSC materials and activities	
CBS	C (communities)	CBSC (communities)
2.2.1	Develop CBSC packs consistent with national policy for health, social and school services and infant care providers and the media (free of charge)	
2.2.2	Present exclusive breastfeeding for 6 months and continued breastfeeding up to 2 years as normal	
2.2.3	Use breastfeeding awareness weeks as an opportunity to stimulate public debate, the	

Pre-service training		Pre-service training
3.1.1	Review and develop standards for breastfeeding education to ensure competency in lactation management	
3.1.2	Review literature and textbooks to ensure that it is in line with policy and practice guidelines	

media and disseminate information2.2.4 Monitor, inform and use all organs of the media and ensure that breastfeeding is

2.2.5 Monitor adequacy of public knowledge,

attitudes and practices on importance of breastfeeding, ways to support and protect it

portrayed as normal

In-se	ervice training	In-service training
3.2.1	Continuing interdisciplinary education based on WHO/UNICEF or other appropriate courses for frontline staff	
3.2.2	Review existing textbooks and literature	
3.2.3	Encourage advanced education in lactation management and to acquire IBCLC or equivalent qualification	
3.2.4	Encourage e-networking amongst breastfeeding specialists	
3.2.5	Monitor coverage and effectiveness of in- service training	
Glol	pal Strategy	Global Strategy
4.1.1	Implement policies and plans based on Global Strategy and WHO/EURO action plans	
4.1.2	Communicate policies and plans to all relevant bodies, groups and organisations	
4.1.3	Monitor progress and evaluate results of policies and plans	
Inte	rnational Code	International Code
4.2.1	Develop EU regulations compatible with the International Code as minimum requirement	
4.2.2	Ensure that International Code is reflected in EU position at meetings of Codex Alimentarius	
4.2.3	Develop national legislation, including mecha- nisms for enforcement	
4.2.4	Encourage full implementation of the International Code even if EU regulations do not require it	
4.2.5	Inform pre and post graduate health profession- als and health service providers	
4.2.6	Develop code of ethics for individual and insti- tutional sponsorship of courses, educational materials, conferences and other activities	
4.2.7	Disseminate information to the public about principles and aims of the International Code	
4.2.8	Phase out distribution of free formula to low income families and replace with initiatives to promote breastfeeding	
4.2.9	Set up monitoring system with responsibility for checking compliance with the International Code; investigate and prosecute breaches; infor- mation for the public and relevant authorities	

In-s	ervice training	In-service training
	Upgrade legislation to support mothers to achieve breastfeeding best practice recommendations	
4.3.2	Ensure sufficient legislative support to enable exclusive breastfeeding for 6 months and continue thereafter	
4.3.3	Extend maternity protection to those not currently entitled (short term contracts, part time etc.)	
4.3.4	Ensure that employers, health workers and public are informed about protection legislation and healthy and safety as applies to pregnant and breastfeeding women	
4.3.5	Inform employers of benefits to them and their breast- feeding employees of facilitating breastfeeding (flexible hours, part time, facilities to express and store)	
4.3.6	Monitor implementation of policies and legislation including maternity protection laws relating to breastfeeding	
Inte	rnational Code	International Code
4.4.1	Ensure collaboration at all levels to establish BFHI as best practice (includes government, National Health System Boards, NGOs, maternity & child care institutions)	
4.4.2	Ensure resources (funding, personnel and time) and technical support for training and assessment	
4.4.3	Encourage maternity units not participating to ensure practice in line with BFHI best practice standards	
4.4.4	Incorporate BFHI criteria into standards for nation- al maternity service quality accreditation system	
4.4.5	Develop systematic approach to conveying breastfeeding information in antenatal period consistent with BFHI	
4.4.6	Involve fathers and families to ensure appropriate support at home	
4.4.7	Improve cooperation between hospitals and other health and social care facilities to ensure adequate lactation support (step 10)	
4.4.8	Ensure adequate training and support in community health and social services	
4.4.9	Encourage implementation of baby friendly prac- tices beyond maternity setting (community, social services, paediatric wards and workplace)	
4.4.1	Draw up protocols to assess hospital and primary care facilities based on BFHI standards	

Supp	ort by trained health workers	Support by trained health workers
4.5.1	Ensure that health and social services staff, including and volunteers, have skills to build maternal ability and confidence	
4.5.2	Encourage and support staff to achieve specialist knowledge and problem solving skills	
4.5.3	Ensure services to support breastfeeding including qualified lactation consultants or other suitably competent health care staff	
4.5.4	Assistance for mothers to provide or acquire breastmilk for preterm or sick infants including assistance for travel and accommodation if unit is at a distance	
4.5.5	Establish centres of excellence as a source for health workers and mothers including free access to web based resources	
4.5.6	Ensure support to women who stop breastfeeding before they had planned to reduce feelings of loss or failure, and help them attain longer breastfeeding with a subsequent baby	
4.5.7	Put in place patient feedback on breastfeeding information and support	

	counsellors and mother-to-mother ort groups	Peer counsellors and mother-to-mother support groups
4.6.1	Establish and increase trained peer counsellors and mother-to-mother support groups especially for women less likely to breastfeed	
4.6.2	Develop, review and update curricula for peer counsellors and mother-to-mother support groups training	
4.6.3	Strengthen cooperation and communication between health workers and peer counsellors and mother-to-mother support groups	

Supp	oort: family, community, workplace	Support: family, community, workplace
4.7.1	Information to support breastfeeding mothers, partners and families including support networks	
4.7.2	Encourage family support through public education and cooperation between National Health System and voluntary sector and other partnerships	
4.7.3	Identify and address support needs of mothers in difficult circumstances or special groups of women, e.g. adolescent, immigrant and other groups	
4.7.4	Encourage breastfeeding friendly policies/ facilities and protect right of women to breastfeed whenever and wherever they need to	

Rese	arch	Research
6.1.1	Foster and support research on breastfeeding, based on agreed priorities, definitions of breastfeeding and free of competing and commercial interests	
6.1.2	Support and ensure exchange of expertise in breastfeeding research among research institutions in EU Member States	

Observations (if any)

Annex 8. Model national policy on infant and young child feeding

- Breastfeeding is a right that everyone will respect, protect and help families accomplish; however, mothers will not be obliged to breastfeed, as putting undue pressure on them to do so is as unacceptable as putting undue pressure to opt for formula feeding.
- All expectant parents will be provided with evidence-based and objective (i.e. independent from commercial interests) infant feeding information in order to ensure they make an informed decision.
- All mothers who decide to breastfeed will be supported to initiate breastfeeding, to breastfeed exclusively for six months and to continue breastfeeding, with appropriate complementary foods, until two years and beyond, or as long as the mother and baby wish.
- Special support for optimal infant and young child feeding will be offered to disadvantaged individuals, groups and communities with low breastfeeding rates and with poor infant and young child feeding practices.
- Because there is no evidence for the superiority or equivalence of formula feeding when compared to breastfeeding, competent health workers will not recommend it as an alternative or a complement to breastfeeding, unless there are legitimate medical reasons for doing so.
- All pregnant women and mothers will be educated and get one-to-one counselling on optimal infant and young child feeding in antenatal classes/clinics and after the birth of their baby.
- Every effort will be made to facilitate mothers in the paid workforce to exclusively breastfeed up to six months and to continue breastfeeding after that for as long as the mother and baby wish, in combination with appropriate complementary foods.
- Before their infants reach six months, all parents will receive information and advice on appropriate complementary foods and when and how to introduce these to their infants' diet.
- After six months, all parents will be advised to introduce and gradually increase the frequency, consistency and variety of healthy family foods, adapting them to the infant's requirements and abilities, while avoiding sugary drinks and foods with low nutrient value.
- All hospitals, maternity units and primary health care facilities will adopt and implement effective strategies for the protection, promotion and support of breastfeeding, such as those included in the Baby Friendly Initiative.
- All health, social and allied workers caring for mothers, infants and young children will get the education, training and skill development required to implement this policy.
- All health, social and allied workers and institutions caring for mothers, infants and young children will fully comply with all the provisions of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA resolutions.
- Collaboration between health workers, lactation consultants, other service providers and other support groups in the community will be encouraged.
- The media will be encouraged to represent breastfeeding and appropriate complementary feeding as the normal, natural and optimal way of feeding infants and young children.
- Comprehensive, timely and accurate data on breastfeeding rates and practices, using standard agreed definitions and methods, will be collected for planning, evaluation and operational research purposes.

Glossary

BIOMONITORING OF BREASTMILK

Breastmilk is often used in human biomonitoring to detect persistent residues of man-made chemicals accumulated in human bodies along the food chain. These contaminants can enter the body through, for example, ingestion, inhalation, tactile contact, etc. It is used as an indicator and a monitoring instrument of fat soluble and persistent substances. Breastmilk is often seen as an easy tool for biomonitoring as it is non invasive, though this is ignoring the fact that it may not be easy for mothers to deliver the needed amount as pumping or expressing breastmilk can be problematic for some women. For these reasons many organisations use breastmilk to monitor levels of environmental pollutants. These organisations all stress that their purpose is not to provide a contraindication to breastfeeding and emphasise that the major health advantages of breastfeeding are not compromised by any potential risk from residues of these contaminants in breastmilk. Also research information to date has not clearly identified a health risk (either clinically or epidemiologically) to the breastfeeding/ breastfeed baby from its mother's exposure to environmental chemical or other contaminants, or to the presence of levels of these environmental contaminants in her breastmilk.

COST/BENEFIT

Cost-benefit analysis estimates the value of the benefits and the costs involved to establish whether projects are worthwhile, that is, whether the beneficial value (e.g. potential improvements in health) of the project is greater than the costs (generally monetary but not always so) involved. Cost-benefit analysis, thus, finds, quantifies and sums up all the positive factors (the benefits) and relates them to the costs to determine a net result indicating whether the project or planned action is justified or advisable.

COST/EFFECTIVENESS

Cost-effectiveness analysis is a technique for comparing the relative value of various clinical strategies. In its most common form, a new strategy is compared with current practice (the "low-cost alternative") in the calculation of the cost-effectiveness ratio. Cost-effectiveness analysis helps evaluate strategy choices where resources are limited. It should be noted that strategies can only be compared if they have similar goals and use outcome measures that can be compared. Being cost-effective does not mean that a strategy saves money, and just because a strategy saves money does not mean that it is cost-effective. The notion of cost-effectiveness also requires a value judgment, as what one person thinks is a good price for an additional outcome, someone else may not.

COMPLEMENTARY FEEDING

The infant receives both breastmilk and solid (or semi-solid) food. This definition does not exclude the baby who is also getting artificial infant formula.

EXCLUSIVE BREASTFEEDING

The infant receives only breastmilk from his/her mother or a wet nurse, or expressed breastmilk, and no other liquids or solids with the exception of drops or syrups consisting of vitamins, mineral supplements or medicine.

FULL BREASTFEEDING

Calculated by adding the sum of babies being exclusively and predominantly breastfed.

IBCLC AND **IBLCE**

An International Board Certified Lactation Consultant (IBCLC) has passed the qualification examination of the International Board of Lactation Consultant Examiners (IBLCE) and undergoes

recertification every 5 years for quality assurance of his/her services. The purpose of the IBLCE is to assist in the protection of the health, safety, and welfare of the public by establishing and enforcing qualifications of certification in lactation management. The IBLCE certify candidates after they have successfully undertaken a competency-based exam, irrespective of the lactation management course followed. The IBLCE was established in 1985 and examines candidates in many centres worldwide and in several languages. Re-certification is mandatory every five years. Qualified IBCLCs must adhere to a Code of Ethics and work according to set Standards of Practice. An independent commission for certifying agencies, in place since 1988, regularly accredits the IBLCE certification process.

INTERNATIONAL CODE

The International Code of Marketing of Breastmilk Substitutes was adopted in 1981 by the World Health Assembly of the World Health Organization. The International Code, and a number of subsequent WHA resolutions, place restrictions on the marketing of all breastmilk substitutes and related products, to ensure that mothers are not discouraged from breastfeeding and that substitutes are used safely if needed. The International Code of Marketing of Breastmilk Substitutes and the subsequent relevant WHA Resolutions are jointly referred to in the Blueprint as the International Code.

MOTHER-TO-MOTHER

Mother-to-mother support means the voluntary support given by experienced breastfeeding mothers to other mothers either on an individual basis or in groups. Some mother-to-mother support groups are self-established and self-training and work relatively independently, while others (e.g. La Leche League, National Childbirth Trust) form part of larger national or international organizations that provide high quality training with accreditation, regular continuing education, best evidence-based information and support, and have clearly defined responsibilities and operational guidelines, including documentation of all activities and regular reporting.

OUTPUTS AND OUTCOMES

Outputs are generally worded in terms of what a programme will provide, i.e. activities, services, events, courses, materials, documents and the like. Conversely, outcomes are generally worded in terms of results, i.e. benefits for the participants. The subject of an outcome should be the beneficiary of a given programme, project or activity, not the programme itself or the programme staff. The final results in terms of health (mortality, morbidity, disability, nutrition) are usually grouped under the word "impact".

PEER COUNSELLOR

Peer counsellors provide breastfeeding support to mothers, usually on an individual basis. Peer counsellors are specifically trained in breastfeeding counselling and may have gone through a certification process. The services of peer counsellors are not available everywhere. Some peer counsellors are trained by health authorities and are paid members of care teams while others work voluntarily.

PREDOMINANT BREASTFEEDING

The infants defined as predominantly breastfeeding are getting most of their nutritional needs from breastmilk but may also be receiving water, water-based drinks, oral rehydration solutions, vitamins, minerals and medicines in drops or liquids, and traditional drinks in limited quantities (e.g. teas). With the exception of fruit juices and sugared water, no food-based fluid is allowed under this definition.

QUANTITATIVE RESEARCH

Quantitative research involves measurements and analysis of numerical data. The aim is to classify

features, count them, and construct statistical models in an attempt to explain what is observed. The quantitative researcher knows in advance what aspects are being studied and what numerical data will be collected. Data is in the form of numbers and statistics, but may miss contextual detail. Quantitative researchers tend to remain objectively separated from their subject matter. If the study size is representative, findings can be generalised.

QUALITATIVE RESEARCH

Qualitative research involves analysis of data such as words (e.g., from interviews), pictures (e.g., videos), objects (e.g., artefacts), or events (e.g., through observation). The aim is to gain insights through a complete detailed description. The research questions and study design may only evolve during respondent interactions. The researcher is the data gathering instrument. The outcome is subjective with the individuals' interpretation (e.g. through participant observation, in-depth interviews) of events paramount. Qualitative data is less amenable to generalisation but is "richer".

RANDOMIZED CONTROLLED TRIAL

A randomized controlled trial (RCT) is the most rigorous way of determining whether a cause-effect relationship exists (between treatment and outcome) and whether a treatment is cost effective. RCTs have several important features: random allocation to intervention groups; patients and researchers remain unaware which treatment is being administered until the study is completed, although such double blind studies are not always feasible or appropriate; all intervention groups are treated identically except for the experimental treatment; patients are normally analysed within the group to which they were allocated, irrespective of whether or not they received the intervention treatment (intention to treat analysis); the analysis is focused on estimating the size of the difference in predefined outcomes between intervention groups. Other study designs, including non-RCTs, can detect associations between an intervention and an outcome. But these cannot rule out the possibility that the association are caused by a third factor linked to both intervention and outcome. Random allocation ensures no systematic differences between intervention groups with regard to factors known and unknown, that may affect outcome. Double blinding ensures that the preconceived views of subjects and clinicians cannot systematically bias the assessment of outcomes. Intention to treat analysis maintains the advantages of random allocation, which may be lost if subjects are excluded from analysis through, for example, withdrawal or failure to comply. Meta-analysis of controlled trials shows that failure to conceal random allocation and the absence of double blinding yields exaggerated estimates of treatment effects.

Notes

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