Fetal monitoring at home in high-risk pregnancy. An integrated clinical and economic evaluation
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Chapter 1 General introduction

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1.1 Development of de-institutionalized care in the Netherlands

Due to demographic developments, epidemiologic changes, technological progress, and increasing health care needs, the use of health care will continue to grow.\(^1\)\(^2\) Combined with autonomous price increases, increasing health care demands lead to rising health care expenditures, both in absolute terms as well as per capita.\(^3\) One option to regain control of the increasing health care use is to implement rigid budget control. Other options to control the use of health care may be directed towards intrinsic changes of the health care system that enhance the system's effectiveness or efficiency. Examples are innovations in treatment practice (e.g. priority setting, development of clinical guidelines) or organizational innovations of the health care system.

This thesis considers one of the most pronounced organizational innovations in Western health care systems, viz. the de-institutionalization of the provision of health care. Besides cost containment, several other social developments converge into de-institutionalization such as the development of new technologies, increasing continuity of care, the individualization of care, the participation of patients in treatment decisions and recognition of patients' preferences, and the strive for de-medicalization. As such, de-institutionalization might be a valuable contribution to accommodate the growing use of health care for specific conditions and for certain modes of care. We consider de-institutionalization in obstetric care, an area in the Dutch health care system in which preferably non-clinical care is provided whereas other countries would apply routine clinical care.

We define de-institutionalization of care as the transfer of the setting of health care from highly specialized medical settings to medically less structured settings. An extreme case is the substitution of care of highly specialized hospital-based teams for treatment at home with minimal support of primary and informal caregivers. Obviously a gradient exists between these extremes, e.g. short-stay in-hospital care, day care, or outpatient care. Our definition contains three essential characteristics. Firstly, de-institutionalization is primarily related to the organizational setting and the permanent availability of personnel and facilities rather than to the profession of the caregivers involved per se. In some modalities of de-institutionalized care, the profession of the caregivers may be identical regardless of the place where care is delivered. Secondly, as the latter examples show, de-institutionalized care does not necessarily result in out-of-hospital care. Thirdly, we distinguish de-institutionalization from de-medicalization, although the former could support the latter.

De-institutionalization of the provision of care reflects a changing perspective on the organization of health care, sometimes with a profound impact on the clinical concepts underlying care. Health care in Western societies is commonly organized as a two-tier system. At the primary care level, general practitioners, district nurses, and – in case of
obstetrics — community midwives provide generalistic care. Primary care is responsible for the provision of information and advice, elementary diagnosis and treatment using — if anything — simple-to-operate portable equipment or devices, and the selection of health risks which subsequently are referred to secondary care. Care at the secondary level is delivered by highly-qualified specialist care providers who are responsible for consultation, diagnosis, and treatment using advanced hospital-based facilities. Tertiary care, e.g. university hospitals or nursing homes, may be regarded as a further specialization of the secondary care level. De-institutionalization predominantly concerns the relationship between the primary and secondary care level.

The development of de-institutionalized care in the Netherlands has been supported by two influential reports: ‘Shared Care, Better Care’ of the Committee for Modernizing Curative Care in 1994, and ‘Transmural Somatic Care’ of the National Council for Public Health in 1995. In 1994, on behalf of the Department of Health, Welfare and Sports, the Committee for Modernizing Curative Care introduced a comprehensive framework for de-institutionalized care. On the one hand, the strict partition between generalistic and specialist care — until then defined by a clear borderline with a steep threshold between professions and institutes — should become less strict and gradually fade, making care more ‘continuous’. On the other hand, increased ‘continuity of care’ should also induce concerted action between generalistic and specialist caregivers. The framework was supplemented with broad implications on policy making, financial, medical, and regulatory aspects. Despite the special position of obstetrics — a disciplin with a longstanding tradition in de-institutionalized care — no special attention was drawn to this field.

The Committee for Modernizing Curative Care presented four basic models for the organization and responsibilities of de-institutionalized care, viz.:

1. The medical specialist acts as a consultant at home. Care and treatment at home are offered and coordinated by generalistic caregivers.

2. Combined care at home. Care and treatment are offered at home both by specialist and generalistic care providers. Each provider has its own task and responsibility is shared.

3. A trained generalistic caregiver acts as a specialist at home. Treatment and care that would otherwise be delivered by specialist caregivers, are now provided at home by generalistic care. The trained generalistic caregiver is fully responsible.

4. Hospital-based transferred care or ‘out-reaching’. The hospital offers specialist care and treatment at home to patients who would otherwise be hospitalized. Eventually, the specialist in the hospital is responsible.

As the second and fourth model illustrate, the transfer of hospital-based care to the home setting does not necessarily imply the transfer of professional responsibilities from a specialist care provider to a primary care professional. Generally, when the care
setting is changed, professional responsibilities and the content of care may or may not be adapted accordingly.

A special case, not covered by one of the four above-mentioned models, exists when the patient is treated in the hospital under the responsibility of a hospital-based primary caregiver.\textsuperscript{5,6} Although this case is an example of 'transmural' care ('outreaching' of primary care into secondary care), it does not satisfy our definition of de-institutionalized care and will therefore not further be addressed.

The implementation of de-institutionalized care was further supported in 1995, when the National Council of Public Health provided specific recommendations on the responsibilities of caregivers, on treatment capacity and resources, and on the financial system in de-institutionalized care.\textsuperscript{7} Close cooperation and collaboration between the various professional caregivers is essential to implement de-institutionalized care. Collectively they have to develop protocols in which care, responsibilities and coordination are described. Caregivers and patients share responsibility in fitting need and supply. The patient is not only a consumer of health care but also a critical partner. Health insurance companies, regional caregivers, and health institutes should cooperate to develop regional agreements on care and financial resources. Moreover, adverse financial incentives should be absent and functional flexibility should be added to the budgetary system that is predominantly sector-oriented or institute-oriented.

Following the 1994 and 1995 reports, many experiments on de-institutionalized care have been initiated by the government, health insurance companies, and third parties such as the Dutch Heart Foundation and the Dutch Cancer Society. With their specific combination of scientific expertise and patient-oriented perspective, these funds have played a pioneering role on the critical appraisal of innovative experiments. The Health Research and Development Council, enacted in 1998, has taken over the coordination and responsibility for experiments on de-institutionalization initiated or financed on behalf of the government. In 1998, the program consisted of more than 200 ongoing heterogenous projects (see Table 1).\textsuperscript{8}

Many of these innovations have been accompanied by scientific assessment of the presumed outcomes or benefits. In addition, many of them have also provided valuable information on the actual implementation of these experiments in practice. The Working Group Quality Research (WOK) has provided an analysis of the critical factors in the implementation stage.\textsuperscript{9} Based on the empirical evidence from this study, we evaluate their approach and address the consequences for implementation in the discussion chapter of this thesis (Chapter 11).

The remainder of this introduction is structured as follows. First, we provide a concise description of the Dutch obstetric care system in section 1.2. In section 1.3, we elabo-
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* I: medical specialist acts as consultant at home; II: combined care at home; III: generalistic caregiver acts as specialist at home; IV: hospital-based transferred care ('outreaching').

** A: prevention; B: diagnosis; C: treatment; D: care.

Table 1. Transmural care projects in the Netherlands

rate on the developments from which de-institutionalization in obstetrics has emerged. Section 1.4 provides an overview of studies on de-institutionalized obstetric care in which domiciliary uterine activity monitoring or antenatal fetal monitoring have been tried. The mode of de-institutionalized care addressed in this thesis is but one of the three modes found in obstetrics. The last paragraph, section 1.5, delineates the structure of the thesis.

1.2. The Dutch obstetric care system

Obstetric care in the Netherlands is organized into three levels of care. Primary care for low-risk women in early pregnancy is delivered either by independent midwives or general practitioners (about 65%). Approximately 50% of them are referred to secondary care antenatally, during labour, or during the puerperium. Secondary care for high-risk women is provided by obstetricians (35%). Tertiary care is delivered by obstetrician-perinatologists in hospitals with neonatal intensive care departments. General practitioners and the majority of midwives offer their services from out-of-hospital offices.
Obstetricians and perinatologists always provide hospital-based care. Provided that the pregnancy is low-risk and proceeds well, the primary caregiver is responsible for all antenatal and perinatal care and for the identification and referral of (suspected) high-risks to secondary care. A low-risk pregnant woman usually delivers at home under the responsibility of a midwife, but if she prefers otherwise she may deliver in the hospital still under the responsibility of an independent midwife (short stay of 24 hours or less). Usually midwives have specific arrangements with delivery departments and maternity wards in hospitals.

The cooperative model between primary and secondary obstetric care in its current form was explicitly described for the first time by Sikkel in 1979. The Dutch insurance system preferentially not only reimburses home-based midwife deliveries but also covers the cost of maternity home care assistance. Hence, the financial system supports home-based care. The fees for midwifery care and interventions are tightly regulated, as is the case in secondary and tertiary care.

The selection of obstetric risks and generally accepted criteria for referral to secondary care were first proposed by Kloosterman in 1968. Originally, high-risk indications were defined in Kloosterman’s list of high-risk conditions and fully incorporated in Dutch obstetric textbooks. Due to technological and professional developments, among others the immanent extinction of the general practitioner as obstetric caregiver, the future of the two-tier obstetric system was questioned in the 1980s. In 1989, the ‘Kloosterman Committee’, a government-initiated working group supervised by the National Health Insurance Board, not only re-emphasized the natural character of uncomplicated low-risk pregnancy (with home as the normal place of delivery). The Committee also stressed the importance of careful selection of obstetric risks and cooperation between all professionals involved in perinatal care. Incentives should be developed to reinforce this option as gradually a shift towards clinical obstetric care could be observed. As part of this, the Committee has also revised the original Kloosterman’s list into the Index of Medical and Obstetric Risks. The Index integrates clinical expertise and formal evidence into institutionalizing and de-institutionalizing guidelines not only for professional caregivers but also for health insurers.

In other Western countries such an Index does not exist because all antenatal and perinatal care are delivered by obstetricians in the hospital. In the United States, home births were common until the Second World War. In the United Kingdom, the government actively promoted hospital births by advocating, in 1959, provisions allowing 70% of all deliveries to take place in the hospital, and in 1970, for all deliveries. Although primary care midwifery in the UK is supported, its natural companion home birth is not. This policy is currently questioned.

In contrast, midwifery in the Netherlands was legally acknowledged as an independent profession in 1865 with caregiving confined to childbirth of low-risk pregnant women and maternity care. Originally, antenatal care, first introduced in the 1910s, was
part of the responsibilities of secondary care professionals. This changed in 1932 with the introduction of midwife-assisted antenatal care from 30 weeks of gestation. Midwife-assisted antenatal care was extended to the first trimester in 1951. The midwife based system in the Netherlands including home birth as primary option was kept vital despite the absence of a national policy on the place of birth and a general increase in specialist care. Probably the general two-tiered organization of Dutch health care with a considerable share provided by primary care, the Medical Practice Execution Act (Wet op de Uitoeefening van de Geneeskunst) (1865), the Health Insurance Act (Ziekenfondswet) (1941), and self-regulation by primary and secondary caregivers have provided a protective environment.

The effectiveness and efficiency of the Dutch two-tier obstetric system have been the subject of several studies. The Wormerveer Study, an evaluation of primary midwifery care and perinatal outcome in low-risk pregnant women scheduled for midwife-assisted delivery between 1969 and 1983, showed that the two-tier system based on the selection of obstetric risks was successful and the resulting perinatal outcome favorable. Primary obstetric care delivered by a selection of general practitioners between 1980 and 1985 reached the same conclusions. Ritceo and Hingstman evaluated the 1987 Index of Medical and Obstetrics Risks. They concluded that almost all general practitioners, midwives and gynecologists accepted the principles of the Index. However, the majority of these caregivers found the implementation of the Index rather unsatisfactory, there was a lack of consensus regarding particular details of the Index and about one-third of the gynecologists refused to accept the Index as guideline. Initially, the use of the Index in practice varied considerably: 82% among midwives, 51% among general practitioners and 18% among gynecologists. Based on the results of the Gelderland Study (1990-1993), Wiegers concluded that perinatal outcome of midwife-assisted home versus hospital deliveries in women at low risk at the onset of the delivery did not differ, thereby showing that home delivery for low-risk women was safe. The feasibility of the system depends on the existence of well-trained professionals, and unequivocal, feasible and largely accepted criteria to identify high-risk pregnancies.

Concerning future developments, Bonsel and Van der Maas, after a formalized panel study, expected no major changes in the structure of the Dutch obstetric system, even if health insurers would promote a private market approach to obstetric care. Due to emancipatory forces, choices in care will grow, leaving a regulating role to the government in case medical and/or economic consequences are regarded undesirable. They acknowledged that socio-cultural developments could alter the organization of care but these would probably not affect the obstetric system in itself. A recent, quite alarming, development is the closing of several community midwifery practices, mainly due to a shortage of midwives and rather unfavorable working conditions. The persistence of this trend may seriously undermine the viability of the system.
As a result of this primary care oriented system, the Netherlands is the only industrialized country with a large share of home-based obstetric care. In 53% of all pregnancies, the midwife or the general practitioner is fully responsible for obstetric surveillance including the delivery. About 30% of all deliveries are home confinements supervised by a midwife or general practitioner and 84% of all postnatal care is given at home by maternity care assistants.\textsuperscript{39} Indirect consequences of this ‘physiological approach’ towards pregnancy and delivery are low intervention rates.\textsuperscript{16,35,40} Although friction inefficiency and in-appropriate use of care may exist for pregnant women referred to secondary care,\textsuperscript{41} any medical disadvantages do not appear from the system. The economic balance may well be in favour of this system as hospital care and the risks of overtreatment are avoided in about 40% of all pregnancies.

The success of the system is based on four elements. Firstly, the legally protected position of highly-educated midwives acting as an independent medical profession with its own financial arrangements. Secondly, the Index of Medical and Obstetric Risks as a generally accepted instrument to separate low-risk from high-risk pregnancies. The Index not only defines the mutual responsibilities of midwives, general practitioners, and obstetricians; it also embodies the basis for concerted action between primary and secondary caregivers. Thirdly, a well-organized maternity home care system. And finally, the physiological perspective on pregnancy and childbirth is generally accepted both by pregnant women as well as by caregivers. These four elements have also stimulated the development of de-institutionalized care.

1.3. Incentives contributing to de-institutionalization

De-institutionalized care has been encouraged for at least five reasons: (1) Technological progress that allows de-institutionalization, (2) increased efficiency, effectiveness and cost containment, (3) superior continuity of care, (4) increased individualization of care and recognition of patient preferences, and (5) de-medicalization. Each development is described from a general perspective. Subsequently, its relevance to obstetrics and de-institutionalized care in particular is explored. Finally, the position of each development in this thesis is addressed.

1.3.1. The development of new technologies

Innovation or the introduction of new technologies or tools may have three separate effects. Firstly, innovation may increase effectiveness through the extension of diagnostic or treatment possibilities. It depends on the specific characteristics of the new technology whether the required inputs have to be expanded or reduced. Secondly, innovation may also be aimed at employing the same amount of inputs more efficiently, maintaining the original level of effectiveness. Finally, innovation may result in diag-
nostics or treatments that increase convenience for the patient or are more easier or convenient to operate, without changing inputs or effectiveness. Increased effectiveness, efficiency, or convenience in operation may each serve as an incentive for the development of new technologies.

Generally, the introduction of improved technology may not only enlarge the diagnostic and treatment options to patients. New technologies often require higher educated personnel and sometimes the availability of complex facilities which frequently are hospital-dependent. Efficient use of complex technologies is an incentive to concentration. Therefore innovation not only tends to encourage institutionalization but may also increase costs.

Innovation may encourage de-institutionalization when specific technological progress allows diagnosis, treatment, or care to become less dependent of setting, personnel, or knowledge. Computerization and miniaturization may facilitate this. Examples are home dialysis equipment, 24h-ECG telemetric monitoring, treatment of deep venous thrombosis using self-injected low-molecular weight heparines (LMWH) which substitutes in-hospital stay for home treatment, or innovations in anesthesiology and minimal invasive surgery that have stimulated day care and short stay surgery.

The shift towards de-institutionalized obstetric care due to innovation has so far been limited. Obviously the share of de-institutionalized obstetric care in the Netherlands is already substantial. More important, both antenatally as well as during childbirth, the set of diagnostic devices is limited (ultrasound, CTG, fetal scalp blood sampling for pH measurements) and basically aimed at monitoring or early detection. Therapeutic options are also limited because, so far, there are few opportunities to alter the course of pregnancy or the fetal condition. In addition, antenatal and perinatal care is labor-intensive and knowledge-intensive, implying few opportunities for labor-saving technological progress. Therefore, obstetric innovations generally strengthen institutionalization (e.g. NICU). Computerization and miniaturization of equipment may be an exception in well-defined circumstances. For example, Malone et al. have experimented with the transmission of digitalised interactive live video ultrasound images and recently, a feasibility study on second trimester teleobstetric ultrasonography in Canada has been completed. As will be shown in section 1.4, domiciliary electronic fetal monitoring – the intervention described in this thesis – originates from these specific innovations.

1.3.2. Efficiency and cost containment

In Western health care systems, budgeting is widely used as a means to control the process of the provision of health care. Approximately two-third of the health care budgets in Western countries is devoted to labor expenditures. As mentioned in section
1.1, budgets will increase in the future not only through the growing demand of health care but also through technological progress and (age-related) wage increases.

There are two basic options to contain increasing health care costs: firstly, increasing budget control (rationing) and secondly, a reconsideration of current health producing activities (priority-setting). The former option, however, is difficult to achieve in view of the growing health care needs. Moreover, the yearly wage rate increases exceed inflation and the growth of labor productivity. Simultaneously there are few opportunities to increase labor productivity or reduce the amount of labor employed (the so-called Baumol-hypothesis\textsuperscript{46,47}), with or without technological progress. Therefore, the budget share of labor expenditures and the amount of labor employed in health care will remain high in the future. The alternative – rearranging existing health producing activities – could take two forms: redefining the mix of health-producing activities by substituting ‘non-health’ or ‘low-health’ productive care (e.g. surgery in day care); or reducing the level of existing activities leaving the activities-mix unchanged (e.g. early discharge programs\textsuperscript{42,48}). Provided there exists an appropriate technique, de-institutionalized care could support both alternatives. From this perspective, it seems that de-institutionalization is zero-priced, a rather unlikely assumption.\textsuperscript{49,50}

Regarding obstetric care, demographic changes, the post-war baby boom and its echoes, and the effects of reproduction at higher ages (more high-risk pregnancies, higher case-load in hospitals) dominate other cost-increasing factors. Unlike the mortality rate, the birth rate is rather unpredictable in the long term\textsuperscript{51} and even in the short term.\textsuperscript{52} So far the effect of technological progress on efficiency and cost containment has been limited (except for NICU, see above). This might change in the future with the development of genetic and new imaging techniques.\textsuperscript{35} The opportunities for increased budget control are even more limited than in other health care sectors (high share of labor costs, relatively low wages, positive incentives needed for prenatal care consumption). Hence, rearranging current activities and the substitution of ‘non-health’ or ‘low-health’ care are even more important. One example is early discharge after a cesarean section.\textsuperscript{53} Another example, domiciliary antenatal fetal monitoring, is discussed in section 1.4.

Economic aspects play an important role in this thesis. Not only the zero-price assumption of de-institutionalization is assessed (Chapter 5), we also measure the consequences of hospital-based and de-institutionalized care for the patients’ relatives and friends (‘family burden’) from an economic and psychological perspective (Chapter 6). In addition, we empirically derive patients’ valuations for different monitoring options.

1.3.3. Improving the continuity of care

Continuity of care is acknowledged as one of the primary process indicators of quality
of care. De-institutionalized care may contribute to improved quality of care if continuity of care is warranted. Integrated de-institutionalized care can only be achieved through a close cooperation between the various caregivers involved, both horizontally (i.e., between physicians and general practitioners, and between district nurses and hospital nurses) as well as vertically (i.e., between general practitioners and district nurses, or between physicians and physical therapists). The definition of responsibilities, development of protocols, training, and the exchange of expertise, skills, and information between caregivers, are all essential to continuity of care. However, increased continuity of care is difficult to achieve without increased financial flexibility within the health care system and an increase in coordination overhead.

Although Dutch obstetric care differs from other health care sectors, the above mentioned arguments essentially also apply to obstetrics. The Dutch obstetric system – probably more than any other sector – hinges on the continuity of care. Concerted action of midwives and obstetricians is encouraged throughout the whole pregnancy and birth process. In 1979, Sikkel initiated a cooperative obstetric system in which midwives, obstetricians, neonatologists, and maternity nurses together provide comprehensive care. In 1990, the Department of Health, Welfare and Sports initiated Cooperative Obstetric Working Groups (Verloskundige Samenwerkingsverbanden), aimed at achieving regional cooperation between professions, practical consensus on the selection of risks, the development of protocols, and the evaluation of obstetric care. The evaluation of 10 regional projects has shown that not only consensus on risk selection has increased but also cooperation and collaboration between professions has improved. The absence of competition between disciplines and the empowerment of midwives appear to be pivotal for success.

If continuity of care is sufficiently guaranteed, de-institutionalized care may be considered when the most appropriate care setting before, during, or after the delivery has to be determined. The Index of Medical and Obstetric Risks indicates which setting and which caregiver suits best depending on the woman's condition. Since its release in 1987, the Index has been refined following new evidence, arguments, and interests. If experiments on de-institutionalized care (see section 1.4) prove successful, the Index may be adapted accordingly.

An empirical study on the continuity of care is not part of this thesis. Continuity is acknowledged, in part, in the studies on preference elicitation (Chapter 9 and Chapter 10).

1.3.4. Enhancing patient participation in decisions; the individualization of care

The physician-patient relationship has changed radically within a few decades. The conventional paternalistic 'doctor knows best'-approach has been gradually replaced with
an attitude which welcomes well-informed patients and active participation in medical decisions. Autonomous well-informed co-deciding patients are not only an ethics-based principle but also legally required according to the Medical Treatments Agreement Act (Wet op de Geneeskundige Behandelings-overeenkomst).

The extent of patient involvement varies between the patient as the sole decision maker (one-way exchange of medical information, the physician only gives medical advice; the patient deliberates and decides) and the physician-expert as the sole decision maker who knows what should be done (one-way flow of medical information, the physician deliberates and decides; no active patient participation). In between these extremes are the 'collegial' model (the patient and physician are equal partners) and, more realistic, the 'shared decision' model (two-way exchange of medical and personal information; the patient brings his values and life-style preferences to the relationship and the physician his medical expertise; both deliberate and decide). Irrespective of the actual degree of involvement, patients who participate in medical decisions are more satisfied than those who have to rely on their physicians and this may contribute to favorable health effects.

The increase in patient involvement has shifted emphasize from societal toward individualized decision making. Both in societal and individualized decision making, preferences or valuations can be used to guide the ordering of mutually exclusive clinical strategies when different (health) outcome measures recommend different strategies (non-dominance). For instance, laryngectomy to treat laryngeal cancer improves survival whereas radiotherapy reduces morbidity and increases health-related quality of life. To reach decisions, mortality (life years gained) has to weighted against morbidity (health-related quality of life) or – if differences in mortality are absent – different aspects of morbidity (dimensions of health-related quality of life) have to be weighted against each other. The aim of assigning valuations to multiple health states is to compare different strategies with different outcomes in terms of one summary health measure (e.g. quality-adjusted life expectancy). Details of this procedure have been elaborated elsewhere. In societal decision making, valuations that reflect society's values are assigned to the health states of each strategy. Other aspects than health, e.g. ethical considerations, the distributional effects of health and justice (equity, equal access), may play a role in societal decision making. In individualized decision making, on the other hand, an individual patient assigns his or hers personal valuations (which may include other people's valuations) to the relevant health and, possibly, other outcomes.

Accepted valuation elicitation techniques are paired comparisons, time trade-off, standard gamble, visual analogue scale, person trade-off, and the contingent valuation method. These techniques differ in several respects: the measurement scale is ordinal or cardinal (paired comparisons), the trade-off may or may not explicitly incorporate
risk (standard gamble), (un)healthy people (person-trade-off) or time (time trade-off), and the (cardinal) measurement scale may be either monetary or not (contingent valuation). Conventionally, valuations are assigned to health states, independent of their duration, on a cardinal scale in non-monetarv units ('utility'). It is assumed that elicited valuations are cardinally measurable and interpersonally comparable.65,66

Applying these methods presumes that preferences or valuations more or less exist and can be elicited successfully with the appropriate tool. Others doubt that patients know what they want and suggest that these methods are merely an aid or first step in the construction of valuations and are capable of shaping patient's values ('the method becomes the message').67 Different techniques yield different valuations, thereby questioning the reliability and validity of these methods.68-70 Valuations may also be sensitive to the amount and content of the information, the 'framing' and processing of the elicitation task71,72 and on the rater whose valuations are elicited (patient, physician, general public, policy maker).73

In many health care decisions, societal preferences and individual preferences coincide. Occasionally, the outcome of individualized decision making strongly contradicts societal preference.74-75 Some decisions are considered predominantly societal whereas others are basically left to individual patients. There is no theory which decisions should be essentially societal and which basically individual: "... the optimal treatment in many clinical situations is a “toss up” that depends on the values patients attach to different outcomes and to the risks of particular procedures."76 Kassirer has identified seven 'utility-sensitive' circumstances in which patients' preferences may be considered:76
1. Major differences in the kinds of possible outcomes (e.g. death vs. disability);
2. Major differences in the likelihood and impact of complications;
3. Trade-offs between long-term and short-term outcomes;
4. Trade-offs involving small chances on grave outcomes;
5. Marginal differences in outcomes between options or equality of outcomes;
6. The patient is highly averse to taking risks;
7. The patient attaches unusual importance to a particular outcome.

An additional case – decision making is left to the patient for reasons of principle or ethics – may be considered part of the last criterion. As few medical decisions are based exclusively on the assessment of health outcomes, we distinguish two types of health care choices – although the borderline between them is not always a sharp one:
- choices that are basically medical; and
- choices that are basically non-medical, e.g. choices related to the individualization of health care arrangements once a basically medical decision has been made ('tailor-made care').

Well-informed individualized decisions can only be made if sufficient, relevant, and
scientifically reliable medical information is available and communicated to the patient in an effective and comprehensible way.\textsuperscript{77} This has proved problematic in routine antenatal screening\textsuperscript{78-82} and in delivery by cesarean section.\textsuperscript{83} Patients generally wish to be informed and actively seek information but that does not imply that they always want to be involved in the actual decision making. Patients predominantly prefer a more passive role in decision participation (i.e. the physician as the primary decision maker) whereas the general public prefers a more active role.\textsuperscript{84-86} Differences in participation preferences between patient groups are largely absent.\textsuperscript{87} Apparently, patients may seek information for other reasons than decision participation ("psychological" autonomy).\textsuperscript{84-87} Opportunities for individualized decisions may be limited in acute care, if reliable information is only scarcely available, if well-founded decisions require a lot of information or complex information which limit the processing of information, or if patients find it difficult to accept final responsibility for treatment decisions and the associated health effects. Patients may also refuse individualized decision making if they do not know what they really want.\textsuperscript{87} Most studies recommend an individualized approach, i.e. information tailored to the individual needs, which demands of physicians to develop communicative skills.\textsuperscript{77,83,88}

The 'doctor knows best'-approach has changed particularly in obstetrics and gynecology where patient's empowerment coincides with women's empowerment. Moreover, the position of Dutch pregnant women is rather unique: if contra-indications are absent, low-risk women may choose their caregiver (midwife or general practitioner) and the place of birth (at home or in the hospital). The latter choice basically is a medical decision but in case of low-risk women there are no medically motivated reasons for the preferred place of birth. At this point, we disregard preferences from the caregiver's perspective.

There are several reasons why the patient's home may be the preferred setting. Home care may reduce medicalization. The home environment and the availability of social support may strengthen the coping and adaptational abilities of the patient. At home, patients' lifestyles can be continued, autonomy is maintained, and patients may decide how normal life is going on and how normal life can be accomodated to the disutilities of the health problem.\textsuperscript{89} Hence, medical solutions for problems that are not even medical are avoided. Opportunities however depend on the suitability of the home environment and the medical indication at hand. Finally, home care may reduce the burden of daily travelling to hospitals, hospital visits or hospitalization particularly in regions with low population density.\textsuperscript{84,90,91}

The preferences for home and hospital birth have been investigated in several studies. The advantages of home birth are: feeling more relaxed, at ease, the home is cosier, and more privacy, not being seperated from the partner, family life or friends, less anxiety for (assumed unnecessary) interventions, a positive effect of the home environment on
coping with pain and on behavior during childbirth, and being in control during labor. The advantages of the hospital setting are: safety, availability of medical facilities and knowledge in case of complications, and avoiding the fear of transportation in case of a complicated home birth. Often mentioned disadvantages of the hospital setting are: many rules, loss of privacy, control and autonomy, and orientation toward intervention and technology.\textsuperscript{92,93} Wiegers showed that strong determinants of the choice to deliver at home were previous home birth, confidence of significant others in home birth, large proportion of home births among significant others, and the expected influence of the hospital environment on childbirth (i.e. mainly ‘social’ factors). The effect of medical variables (general health, symptoms, obstetric history) and psychological factors (negative experiences, positive feelings) were modest.\textsuperscript{34}

The strong effect of social factors points toward the ‘societal acceptance’ of home birth. This differs greatly from other Western countries where childbirth traditionally takes place in hospital-based labor wards. Foreign experiments with de-institutionalized midwifery and maternity care show that preferences for home birth are related to safety, being in control, continuity with family life and familiarity of the home, and to psychosocial factors (confidence, anxiety, expectations, bonding).\textsuperscript{34,94} The fact that one-third of the women deliver at home and even a greater percentage initially plans to do so, confirms that pregnancy and delivery are regarded physiological events. Feelings of autonomy and being aware of pregnancy as a physiological event probably in itself stimulate the normal progress of labor.\textsuperscript{40}

Other basically medical choices in obstetrics are options for antenatal screening, planned delivery, epidural analgesia during labor and, in some countries, the option to deliver by cesarean section. Basically non-medical choices relate to the birth process (e.g. ‘under water’ delivery, vertical delivery) and maternity care options. These choices constitute a subtle balance between efficiency of care and individualization of care.\textsuperscript{76,95,96}

Although the advancement of individualized decision-making is generally considered desirable, the potential disadvantages need further investigation. Little is known about patients’ ex ante and ex post satisfaction with their new role. Moreover, there is little information on how the patient’s social environment (family, relatives, friends) reacts to de-institutionalized care, particularly if a change of care-setting translates into a greater involvement or even active participation. Altruism may have its limits in terms of financial or immaterial costs.

The advantages and disadvantages of de-institutionalized care, the strength of preference, and the determinants of preferences, are the main topics of the second part of this thesis (Chapters 7, 9 and 10). We apply an economic and decision-analytic perspective to quantify preferences and relate our findings to the discussion of efficiency versus individualization.
1.3.5. De-medicalization

De-medicalization of care is repeatedly mentioned as a major advantage of de-institutionalization. Medicalization is defined as the process to interpret or reconceptualize a human condition as a medical phenomenon as judged from a biomedical perspective.\textsuperscript{97,98} Medicalization has four characteristics. Firstly, the application of a disease model to interpret a condition, thereby assigning a biomedical emphasis to that condition. Consequently the condition is reinterpreted as disease-like or potentially pathological and defined around the individual's identity of being a patient. Secondly, rational scientific methods and instrumentation are applied to obtain expert-knowledge. Thirdly, scientific knowledge replaces alternative modes of information or knowledge such as experience-based knowledge. The ‘patient’ may experience or report symptoms but cannot know with certainty; it is the physician's ability to ‘diagnose’. And finally, deviations from ‘normality’ – a concept defined on the basis of scientifically determined standards – legitimate diagnosis and treatment.\textsuperscript{98} Possible consequences of medicalization are the loss of autonomy and self-esteem, dependence on expert-knowledge and technology, and an asymmetric patient-physician relationship. Although medicalization is often used to characterize the progress of medicine in an undesirable way, the concept in itself is essentially neutral.\textsuperscript{97}

In the early 20th century, routine medical prenatal care in the United States and the Netherlands did not exist. Midwife-assisted labor and deliveries in the United States were common (about 40% in 1913 but considerably higher in rural areas and among ethnic minorities). Women only consulted a physician antenatally in case of severe complications. About 1940, routine medical prenatal care was still largely absent and midwife-assisted deliveries had fallen to 20%.\textsuperscript{98} Unlike the United States, midwifery in the Netherlands was legally recognized as an independent expertise in 1865 with professional responsibilities confined to uncomplicated childbirth and maternity care. Prenatal care delivered by physicians was first introduced in the 1910s. Originally midwives were not authorized to provide prenatal care. This changed in 1932 when midwife-assisted prenatal care from 30 weeks of gestation was introduced on a legal basis. Midwife-assisted prenatal care was further extended to the first trimester in 1951.\textsuperscript{25}

Obviously, community midwifery in the United States and the Netherlands has developed totally different. Barker holds the deliberate negation of community midwifery, the intentional advancement of physician-guided medicalization of pregnancy, and the acceptance of the medicalization of pregnancy by the general public responsible for this shift.\textsuperscript{98} In the Dutch two-tier obstetric system, de-medicalization is maintained by the physiological perspective on obstetrics. Pregnancy and childbirth are regarded as physiological, natural processes ('healthy disease') which, as a principle, should not be subjected to medical intervention or medical interpretation. Home births and low cesarean section rates are but a consequence of this approach. The early legal recognition of community midwifery as an independent profession (professional auton-
omy), legally defined responsibilities, high educational standards, professional attitudes and financial independence have provided a protective environment against unnecessary medicalization.

De-medicalization is generally regarded as preferable, provided that health outcomes are not affected. De-institutionalization of care might contribute to de-medicalization if ‘normality’ and societal acceptance of the unusual are enhanced. But de-institutionalized care might also advance medicalization if the concept of ‘normality’ is adversely affected. However, the increase of medicalization may be preferable from the patient’s perspective. The initiatives on cardiotocography-based de-institutionalized obstetric care discussed in section 1.4 are reviewed for their de-medicalizing potential.

Chapter 5 of this thesis addresses the de-medicalizing merits of home-based care for high-risk pregnancies. Whether patients appreciate in-hospital monitoring or prefer de-institutionalised monitoring at home is the subject of Chapter 9 and Chapter 10.

1.4. CTG-based de-institutionalization of obstetric care: the empirical evidence

Several studies have been published in which the portable domiciliary electronic monitoring technique has allowed the de-institutionalized obstetric care. Despite considerable heterogeneity, three basic modes of de-institutionalized hospital-based care can be distinguished, each with its own high-risk patient group, indications and specific provision of care:

1. Pregnant women with premature preterm rupture of membranes (PPROM) at risk for preterm birth and/or infection. Regular check-ups may be executed by the pregnant woman herself.
2. Pregnancies complicated by impending preterm labor. Uterine contraction activity is monitored at home in pregnancies at increased risk for preterm birth.
3. Pregnant women with an identified risk for fetal distress and an indication for clinical surveillance. De-institutionalized care includes domiciliary antenatal fetal monitoring, often with home visits.

Below we summarize the available evidence for each of these modes of de-institutionalized antepartum obstetric care. Cardiotocography is also applied in a fourth category, viz. intrapartum monitoring. As intrapartum monitoring is not provided in de-institutionalized settings, that mode of care will not be discussed here. Moreover, we will digress upon the third category – monitoring women at risk for fetal distress – because that mode of care closely resembles ours.
1.4.1. Care for pregnancies complicated with premature preterm rupture of membranes

In 1993, Carlan et al. reported a study on home versus hospital surveillance of women with prelabor preterm rupture of membranes (PPROM, rupture of membranes before labor before 37 weeks of gestation).99 Eligibility criteria were: singleton-pregnant women with PPROM who had not entered labor within 72 hours after rupture, absence of intra-amniotic infection, cephalic presentation, at least one vertical pocket of amniotic fluid greater than 2 cm, cervical dilatation less than 4 cm, and living in a circumscribed area. After 72 hours, women who met the inclusion criteria were randomly assigned to home or hospital management. Both strategies provided identical care: bed rest and pelvic rest, temperature and pulse recorded every 6 hours, daily charting of fetal movements, ultrasound and visual cervical examination once a week, a CTG and blood count bi-weekly. Cervical cultures were treated with antibiotics. Women were hospitalized if there was evidence of labor, chorioamnionitis, or non-reassuring surveillance. Delivery was pursued at 37 weeks if the cervix was favorable. No woman would progress beyond 40 weeks. The high-risk obstetric clinic was responsible for home surveillance. Of the 368 women admitted with PPROM, only 67 women (18%) were included of whom 55 women were actually randomized. 208 eligible women (60%) were not included for having entered labor within 72 hours; 7 women (2%) refused participation for unknown reasons. The length of the latency period (the period between the PPROM and the delivery) and gestational age at delivery were equal between the strategies. Four pregnancies in the home group and three in the hospital group were complicated by chorioamnionitis. Nine pregnancies in the home group and seven in the hospital group had variable decelerations. Two neonates in the home group and one in the hospital group died perinatally. Other neonatal outcomes (birth weight, NICU admission, pneumonia, respiratory complications, enterocolitis, positive blood cultures) did not differ significantly. Neonatal days in hospital and neonatal hospital charges did not differ significantly by surveillance strategy. However, the mean (SD) maternal hospital stay was significantly lower in the home group (7.7 days [5.4 days] vs. 14.6 days [12.9 days]), as were mean [SD] maternal charges ($5388 [$3105] vs. $10395 [$5383]).

It can take several weeks before women with PPROM give birth, i.e. the latency period can be quite long. Hence, the rationale for this study is the potential to avoid unnecessary hospitalization but only feasibility and safety of home surveillance are investigated. The study shows that home surveillance is feasible and reduces maternal in-hospital stay and financial charges. However, statistical power is too low to establish the equivalence of neonatal outcomes ('safety'). Moreover, the low inclusion rate questions the generalizability of the findings. In the Netherlands, approximately 6,000 pregnant women (3% of all pregnant women) experience PPROM. If only 20% of them are eligible for home surveillance, it is uncertain whether the implementation of a nation-wide program would be worthwhile or inefficient.
1.4.2. Care for pregnancies at risk for preterm labor

Preterm birth is an important cause of infant morbidity and mortality. Impending preterm birth is diagnosed as frequent uterine contractions combined with progressive cervical dilatation. Intervention programs have been developed to enhance the detection of women at risk for preterm labor, based on the assumption that preterm labor can be identified before the cervical dilatation advances (> 4 cm), and that they may experience greater benefit from tocolysis.100

In 1986, Katz reported on an electronic ambulatory home uterine activity monitoring system (tocodynamometry) to diagnose uterine contractions in women at risk for preterm labor and birth.101 Prelabor uterine activity was recorded daily by self-monitoring in 76 women at increased risk. Seventy-six (76) women matched for risk factors were selected as controls. 88% of the monitored women and 59% of the controls delivered at term. This study indicates that home uterine activity monitoring is feasible and effective in detecting preterm labor in an early stage.

Randomized controlled trials have compared uterine activity monitoring by tocodynamometry (twice an hour daily) with self-surveillance (instructions on the early symptoms of preterm labor and palpation techniques to detect uterine activity) in women with previous preterm delivery, multiple gestation, cerclage, uterine anomaly, cone biopsy in history, and > 2 second-trimester abortions in history. Monitoring started at 24 weeks and continued to 37 weeks or until the onset of the delivery if the delivery occurred before 37 weeks of gestational age. Women allocated to the intervention group used a home uterine contractile activity monitor to record and transmit uterine contractile activity data daily to the hospital or a monitoring center. Daily telephone contact with a trained study nurse after transmission of the data was part of most strategies.102-106 Home visits by a community midwife once or twice a week in the monitoring and the control group were part of another study.107 Critical reviews and meta-analyses of home uterine activity monitoring studies have raised methodological concerns on the study design, power, randomization, blinding, and detail of study methods.

In 1993, the US Preventive Task Force reviewed seven published, peer-reviewed, studies on home uterine activity monitoring.108 Three randomized clinical trials found no significant effect on the incidence of preterm birth or low birthweight but sample size may have been inadequate to detect a difference.102,103,106 One observational study and three other clinical trials reported a significant reduction in the incidence of preterm birth, neonatal morbidity, mortality, and low birth weight in home uterine activity monitored pregnancies.101,104,105,107 The Task Force concluded: "There is insufficient evidence to recommend for or against home uterine activity monitoring as a screening test for preterm labor in high risk pregnancies. Further research is needed to demonstrate
clearly whether home uterine activity monitoring is effective in improving important clinical outcomes such as neonatal morbidity and mortality.\textsuperscript{109}

In 1995, the same studies (excluding Katz et al.’s observational study) were assessed in a meta-analysis.\textsuperscript{110} Effectiveness of home uterine activity monitoring was assessed in terms of preterm birth, impending preterm labor combined with cervical dilatation > 2 cm, infant admitted to the neonatal intensive care unit, and mean birth weight. An adverse outcome was defined as the onset of preterm labor with cervical dilatation > 2 cm, implying limited opportunities to intervene and to alter the course of the delivery. The odds ratio of preterm birth was 0.85 (95% confidence interval (CI): [0.68 to 1.05]). When stratified for singleton and twin pregnancies, the odds ratio in singletons decreased (0.76, 95% CI: [0.59 to 0.98]), suggesting a 24% reduction in risk of preterm birth in singletons using home uterine activity monitoring. If adverse outcome is defined as preterm labor and/or cervical dilatation > 2 cm, the risk reduction is only statistically significant for the home monitored twin pregnancies (0.48, 95% CI:[0.25 to 0.78]). No significant difference in NICU admissions was found.

The beneficial effect of home uterine activity monitoring in the meta-analysis is not necessarily at odds with the report of the US Preventive Task Force. In a meta-analysis, data are pooled and studies with more cases are assigned a greater weight. In contrast, the qualitative approach of US Preventive Task Force assigns equal weight to studies of different size. As differences in effectiveness are likely to be small, the latter approach is at the disadvantage of finding an effect. A key issue regards the nursing contact alongside the home uterine activity monitoring that was absent in the control group. Therefore, it remains unclear whether any effect is due to home uterine activity monitoring or to the nursing contact.

In 1995 the Collaborative Home Uterine Monitoring Study Group (CHUMS) reported a multicenter randomized double-blind controlled trial of home uterine monitoring in women between 24 and 36 weeks of gestation and at high risk for preterm labor or preterm birth.\textsuperscript{111} Included were women with abdominal surgery during pregnancy, DES exposure in utero, diabetes mellitus, fetal malformations, hypertension, multiple gestation, third-trimester bleeding or placenta previa, polyhydramnios, prior preterm labor or birth in a previous pregnancy, recurrent midtrimester abortion, or uterine or cervical malformation or incompetence. Eligible women (n=1292) were randomly assigned to home uterine activity monitoring twice a day including a nursing contact with either active devices (n=574, data revealed) or sham devices (n=591, data concealed) devices. 127 randomized women were not monitored for unknown reasons and 321 women discontinued study participation. Outcomes were the mean cervical dilatation, the mean change of cervical dilatation from a previous visit at preterm labor diagnosis, preterm birth rate, and infant outcomes. No significant differences in these outcomes were found.

CHUMS concluded that home uterine activity monitoring, if added to daily nursing
contact, was not associated with less preterm birth, higher birth weights, higher gestational ages at delivery, or fewer infant complications. This conclusion corresponds with the 1996 Committee Opinion of the American College of Obstetricians and Gynaecologists: “Based on the results of several studies, there is no reason to implement home uterine activity monitoring”\(^\text{112}\). Uterine activity monitoring as studied is not effective in preventing preterm birth, regardless whether the women are monitored at home or in the hospital.

In 1998, Dyson et al. reported the outcomes of a multicenter randomized controlled trial\(^\text{113}\). Of the 3455 pregnant women at risk for preterm labor, 348 women (10\%) were recommended not to participate and additionally 627 women (18\%) declined consent. Of the remaining 2480 women, 2422 women (including 844 twin pregnancies) were actually randomized to (i) weekly telephone contact with a nurse (n=798); (2) daily telephone contact with a nurse (n=796); (3) daily telephone contact with a nurse plus home uterine activity monitoring (n=828).

All women were educated about the symptoms of preterm labor. Moreover, all women were asked to record symptoms and contractions in a daily log. Women in the weekly-contact group were asked to assess themselves for symptoms of preterm labor and palpate for uterine contractions twice a day. A nurse from a perinatal service center called the women once a week to evaluate their logs and encourage self-assessment. If symptoms or contractions persistently exceeded predefined thresholds, women had to contact their obstetrician. Care in the daily contact group was identical to the weekly group except that the perinatal center-based nurse now contacted the women once a day and assisted them to contact the obstetrician if symptoms or contractions persisted. Care in the monitoring group and daily contact group was the same.

In addition, women in the home monitoring group were asked to monitor the uterine activity for two hours daily using portable equipment (Corometrics 600, Corometrics Medical Systems, Wallingford Conn.). Data were transmitted by telephone and evaluated instantly at the perinatal center. In case of referral, obstetricians and nurse practitioners were asked to adopt the following guidelines: evaluation of cervical dilatation, specific criteria for diagnosis of preterm labor, and, if necessary, aggressive use of tocolytic drugs before 35 weeks’ gestation.

Preterm labor < 35 weeks’ gestation was diagnosed more often in the home monitoring group (p=0.06). The incidence of preterm birth < 35 weeks (approx. 14\%), preterm labor < 35 weeks (approx. 24\%), cervical dilatation, gestational age at preterm labor and at delivery, did not differ significantly between the strategies. Neonatal outcome (neonatal mortality [approx. 5\%], birth weight, NICU admissions, length of hospital stay) did not differ significantly between strategies. However, the mean (± SD) number of unscheduled visits to obstetricians differed significantly by strategy: from 1.2 ± 1.5 in the weekly-contact group to 2.3 ± 2.3 in the home-monitoring group (p < 0.01). Nineteen percent (19\%) of the women in the home monitoring group vs. 13\% in the other groups received tocolytic drugs after symptoms (p < 0.01). Moreover, 24 women treated with tocolytic drugs had complications.
In summary, there is no incremental benefit from adding daily nursing contacts or home uterine activity monitoring to an early detection program consisting of proper instruction, daily self-assessment, and weekly nursing contact. Intensifying the early detection of preterm labor increases care and costs but does not improve neonatal outcome. This finding is not fully unexpected. Early detection only results in improved outcome if an effective treatment exists. However, the prevention of preterm birth by tocolytic drugs beyond 34 weeks' gestation lacks firm evidence. Only about 15% of the women enrolled in this study fell within this range. Moreover, tocolytic drugs are only effective when other measures to improve neonatal outcome are available, e.g., corticosteroid treatment to enhance pulmonary maturity or birth centres equipped with preterm delivery facilities.

Preterm labor and birth are important causes of perinatal morbidity and mortality. Uterine activity monitoring may support the early detection of preterm labor. Hence, the primary aim of monitoring women at risk for preterm labor is to improve obstetric and neonatal outcome. Monitoring at home to increase convenience may be a secondary aim. Currently available studies provide insufficient evidence that home uterine activity monitoring, even if the early detection of preterm labor is advanced, results in a reduction of preterm birth and superior neonatal outcome. Current treatment policy is therefore aimed at tertiary prevention (treating the patient given the existence of an injury) instead of secondary prevention (identifying and treating at risk patients). As Dyson et al. show, uterine activity monitoring is not effective for the early diagnosis of preterm birth. Probably preterm activity monitoring is not effective for the early detection of preterm birth. Probably preterm or high-risk pregnancies that conventionally require clinical surveillance.

**Antenatal fetal monitoring: the technique**

Long distance transmission of biomedical data by telephone lines dates from the late 19th, early 20th century. Computerized analysis of fetal heart rates was developed, among others, by Dawes et al. In 1983, Dalton described a technique to transfer fetal heart rate tracings from the women's home to the hospital using the public telephone network. Audible fetal heart sounds were relayed in real-time from patient's homes, with demodulation and computer processing (using the TELEPLOT system) in the hospital. In 1983, Dawson and Gough started the development of a digital system for rapid transmission of compressed data (the narrow beam CEUSPEC system). A modified microprocessor-based version was developed by Gough in 1986, the broad beam (Huntleigh) Domiciliary Fetal Monitor (DFM). The DFM consists of a remote data collection unit and central receiving microcomputer. Reduced data can be transmitted to the hospital using the public telephone network in 40s, providing a visual fetal heart rate...
trace for immediate assessment. In a variant of this system, the broad beam HOME-PLOT, transmitted data are directly fed into a conventional Hewlett Packard HP8040 cardiotocograph with high-quality autocorrelation for signal processing, eliminating the need for advanced computer processing. With the introduction, in 1989, of a commercially available software package (Oxford Sonicaid System 8000, Oxford Sonicaid Ltd, Chichester, UK), the domiciliary antenatal fetal monitoring has fully matured. The equipment for fetal home monitoring consists of a central receiving personal computer and several portable fetal monitors. Fetal heart rates, fetal movements, and uterine activity are recorded and stored at home. Data are sent immediately by modem to the receiving computer were they are analyzed in terms of record quality, uterine contraction peaks, basal heart rate, variation, accelerations and decelerations.

Clinical relevance
Several studies have demonstrated an association between fetal heart rate variation and fetal oxygenation and between loss of variability or non-reactive fetal heart rate patterns and adverse neonatal outcome. Reference ranges for fetal heart rate variation in second and third trimester pregnancies are available. Fetal heart rate monitoring is generally used as a screening test rather than a diagnostic test. The obstetrician needs a test that correlates well with perinatal outcome with minimal intra-observer and inter-observer variability. Flynn et al. found a sensitivity of 86% (false negative rate: 14%) and a specificity of 89% (false positive rate: 11%) from which follow a predictive value of a positive test (PV+) of 15% and a predictive value of a negative test (PV−) of almost 100%. Another study reported more favorable test characteristics: sensitivity: 70%; specificity: 95%; predictive value of a positive test (PV+): 85%; predictive value of a negative test (PV−): 90%. Flynn et al. also found low intra-observer variability (1/40 CTGs) and low inter-observer variability (3/40 CTGs). Therefore, a normal fetal heart rate is almost always predictive of a healthy fetus but the reverse is not. Although the fetal heart rate may be regarded a proxy of fetal well-being, it should be part of a clinical, biochemical, biophysical and biophysiological assessment.

Studies in the United Kingdom
Dalton et al. have demonstrated the technical feasibility of domiciliary monitoring. Although using different techniques, both Dalton and Currie and Feijen showed that domiciliary monitoring was practically feasible among a larger group of pregnant women and that their systems were reliable despite the signal loss (5%-13% in the broad beam transducer TELEPLOT system versus 37% in Feijen's small beam transducer system). Both studies recommended direct communication between supervisor and pregnant women.

Another ‘real practice’ test was conducted by Dawson et al. using the Huntleigh DFM system including a fetal event marker to record fetal (in)activity. Monitoring was performed either by the pregnant women themselves and supervised by telephone by
a hospital-based midwife (45%) or monitoring was executed by midwives during home visits (55%). Fetal heart rates were subsequently transmitted to the hospital where they were computer analyzed. Recordings of poor quality were either repeated or the woman was brought to the hospital. 1120 recordings in 74 women (10 healthy volunteers and 64 pregnant women at high risk) were made. Three women (4%) could not be instructed to record their own fetal heart rates and 18 women (24%) had no telephone. For unknown reasons, the obstetrician reviewed the recordings at 11 occasions at the woman's home. Eleven of the 1120 transmissions (1%) failed and 13 recordings were uninterpretable (1%). During the developmental stage, several other problems were encountered: failed arrangements between monitoring midwife and pregnant woman (n=34), poor modem operation (n=55) and other, mainly equipment failure (n=47). All problems could be solved satisfactorily. All but one woman complied to the scheme. Domiciliary monitoring did not fail to detect any adverse condition.

The authors conclude that the system is convenient, safe and efficient. Although, inclusion of a fetal event marker was useful, the performance of this system relative to previously developed systems remains unclear. The study also shows that most women are prepared and able to make their own unsupervised recordings after adequate training. The excellent compliance is in part explained by the role of the midwife: women should not receive isolated monitoring at home. The visiting midwife is not only a 'monitoring technician' but should also act as a professional caregiver, provide advice and encouragement at home, and serve as liaison between the woman and the obstetrician. The author's claim that hospital admissions and clinic visits have been reduced is likely but not substantiated with data.

James et al. have implemented domiciliary monitoring in four UK centers, each with its own organization. In Bristol, midwives record the fetal heart rates usually at one of five local health centers. In Glasgow, recordings were made by midwives and subsequently transmitted from the women's homes or from the regional hospitals to the fetal assessment unit in Glasgow. In London, the monitoring equipment is given to the pregnant women after initial training. Women record the fetal heart rates at their own homes and transmit the recordings by telephone. And finally, in Nottingham, midwives record the fetal heart rate traces at the women's homes during a home visit, usually twice a week. In all centers, transmissions were made within 3 hours of the recording to the assessment unit. Additional monitoring or tests were allowed if indicated by the obstetrician. In case of 'abnormal' fetal heart rate traces, a woman should attend hospital for conventional CTG-monitoring and/or additional tests. Recordings of low technical quality were repeated.

Included were 368 high-risk women with an indication for fetal heart rate monitoring (reduced fetal movements, hypertension, previous stillbirth, post-term pregnancy, poor maternal weight gain, small for dates, or antepartum hemorrhage). 825 transmissions were made of which 769 (93%) were sent successfully. Fifty-six attempted transmissions were unsuccessful due to problems with telephone lines (40/56), interruption
of calls (3/56), incorrect operation of the equipment (9/56) and technical problems (4/56).

The acceptance rate ranged from 71%-80%. Tracings were 'non-interpretable' (acceptance rate < 75%) in 38 out of 825 recordings (5%). Eight recordings, initially labeled as uninterpretable, were later classified as interpretable by the obstetrician due to inexperience with domiciliary monitored traces compared with conventional CTG-traces. This points towards the importance of experience in the assessment of CTGs made on different equipment.

The aim of the study was to evaluate the system rather than the outcome of antenatal fetal monitoring. The system was feasible but proved vulnerable to telephone communication. Unfortunately, comparisons on the organization of domiciliary monitoring between centers are lacking. The advantages and disadvantages from the woman's and hospital's perspective are discussed. As the workload of hospital staff is reduced but the already heavy workload of community midwives is increased, it is important that most pregnant women are capable of operating the equipment after instruction. This opens opportunities for domiciliary self-monitoring, a recommendation not shared by others.133

In 1989, Dawson et al. reported a randomized study comparing domiciliary antenatal fetal monitoring versus conventional in-hospital monitoring.135 Sixty-five high-risk pregnant women (suspected IUGR, hypertension, antepartum haemorrhage, poor obstetric history, reduced fetal movements, or unexplained weight loss with proteinuria) were invited for participation. Five women (7.6%) preferred in-hospital monitoring and refused participation. Women with multiple pregnancies or women not having a telephone were excluded. The remaining 60 women were randomly assigned to domiciliary monitoring (n=41) or hospital monitoring (n=19). Domiciliary monitoring consisted of home visits by a hospital-based midwife who recorded the fetal heart rates and transmitted them by telephone to the hospital. In addition, women had to visit the antenatal clinic regularly. The hospital-based referring consultant team was responsible for the domiciliary monitoring scheme and all medical decisions including the duration and frequency of the home visits. Women in the hospital group received conventional care. Women in both groups should deliver in the hospital.

Obstetric and neonatal outcomes did not differ by monitoring modality. The hospital group on average spent 27.1 days (range 2-78) in observation versus 25.4 days (range 1-80) in the domiciliary group. Hospitalization could be avoided in 21 women (53%) in the domiciliary monitoring group. Sixteen percent (16%) of the observation period in the domiciliary group and 50% in the in-hospital group were spent as inpatient days. If all eligible women would be domiciliary monitored, 345 in-hospital days would be saved. Evaluation of the domiciliary program, assessed by questionnaire at the end of the pregnancy, did not reveal any major dissatisfaction with the scheme.

The main aim of domiciliary monitoring was to shorten or even avoid hospitalization, assuming that most women prefer home to hospital care. This study indicates that
women largely accept domiciliary monitoring and that domiciliary monitoring reduces hospital admissions and the length of in-patient stay. However, as the sample size is small, the equivalence of obstetric and neonatal outcomes is inconclusive.

In 1990, Lindsay et al. reported on an uncontrolled prospective cohort of 134 women included in a domiciliary fetal monitoring program. Eligible were women with at least 28 weeks of gestation and one of the following indications: current/previous intrauterine growth retardation, reduced fetal movements, postdate women, gestational diabetes, previous stillbirth, mild hypertension, loss of or failure to gain weight, and several minor indications. Clinical surveillance was not always required. Women themselves recorded the fetal heart traces and transmitted the traces by modem to the hospital. The technical quality of the traces was assessed by a hospital-based obstetric nurse/midwife. All traces were evaluated by a trained obstetrician on call. Women with abnormal traces received conventional cardiotocography in the hospital. The induction rate was 28% in monitored women versus 15% in a reference group of women admitted to the perinatal unit. The mode of delivery did not differ between these groups. Perinatal mortality did not occur. The obstetric outcome of the monitored women was similar to that of the women who were perinatally hospitalized.

Domiciliary self-monitoring is technically feasible and acceptable to pregnant women. One woman (1/134) refused domiciliary fetal monitoring. Five women (5/134) were incapable of handling the monitoring equipment. The high-risk pregnancies included in this study would, under normal circumstances, not require hospitalization. Lindsay et al. suggest that domiciliary monitoring is advantageous to the women (no travelling, no time consuming hospital visits, no hospital admissions, less inconvenient for the women and their families) and to the caregivers (releasing outpatient and inpatient resources and midwifery expertise, increasing quality of care). Original data on these aspects were not presented.

Studies in the Netherlands
Since 1992, four studies on domiciliary antenatal fetal monitoring have been conducted in the Netherlands. Two studies are observational open uncontrolled studies, conducted at the Beatrix Hospital, Gorinchem, and the Drechtsteden Hospital, Dordrecht, respectively. The other two studies are randomized controlled trials, one conducted at the University Hospital Utrecht, described below, and the other conducted at the Academic Medical Center, Amsterdam, which is reported in detail in this thesis.

A fifth experiment was initiated by Perinatal Services Netherlands – a company that offers nation-wide hospital services including domiciliary monitoring – on a commercial basis. As the inclusion criteria, data on eligible women, and obstetric outcomes, are unknown this study has been excluded from this survey.

In 1992, the Beatrix Hospital, Gorinchem, started domiciliary antenatal fetal monitoring as part of a larger home care technology innovation program consisting of diagnostic,
treatment and care technologies for various patient groups. The program was initiated by the primary home care organization in cooperation with the local general practitioners, hospital-based gynecologists and nurses. Included were moderate at risk pregnancies with an indication for clinical surveillance (diabetics, Hb and IUGR). Contra indications were bad obstetric history and an unsuitable home situation. 139

The obstetrician is responsible for prescribing the monitoring policy (cardiotocography once a day, every other day, or twice a week). Fetal heart rates are recorded during a home visit and send by modem to the hospital where they are analyzed using SYSTEM 8000 software. All traces are assessed initially by an obstetric nurse and are subsequently reviewed by an obstetrician. In case of suboptimal fetal heart rates, the obstetrician is informed. If necessary the woman is referred to the hospital to assess the fetal condition. Women are weekly seen at the antenatal clinic for routine pregnancy surveillance. Two models of care have been tried. In the first model, intake of eligible women and domiciliary antenatal fetal monitoring are executed by primary care district nurses. In the other model, district nurses are responsible for the intake but women are antenatally monitored by trained hospital-based nurses. In both models, the general practitioner is the first to be contacted if women have questions or if they suspect complications. On average 45 women are monitored at home each year.

In 1992, a domiciliary monitoring program for moderate at risk pregnancies was started at the Drechtsteden Hospital, Dordrecht. Included were women who needed at least three times weekly antenatal fetal monitoring at the outpatient clinic, i.e. pregnancies complicated with hypertension, IUGR, diabetes mellitus, or a previous complicated pregnancy. An indication for clinical surveillance is not necessary. Self-monitoring consists of the recording of antenatal fetal heart rates by portable cardiotocography. Traces are send by modem to the hospital were they are analyzed using SYSTEM 8000 software. Traces are evaluated by trained hospital-based nurses. The nurse contacts the women by telephone, i.e. home visits are not included. Women are weekly seen at the antenatal clinic by an obstetrician for routine antenatal surveillance. On average 35 women are monitored each year.

This program leads to modest de-institutionalization of care, as clinical surveillance is not indicated.

In 1996, the results of a multicenter randomized controlled trial conducted at the University Hospital Utrecht were reported.138 Included were 415 women with pregnancy induced hypertension (diastolic bloodpressure ≥ 100 mmHg with or without albuminuria), suspected fetal growth retardation with an ultrasonic measured abdominal area below 5th percentile and/or a suboptimal umbilical artery wave form, post term pregnancies (gestational age ≥ 42 0/7 weeks), and high risk preterm birth (including PROM) without intravenous tocolysis. Clinical surveillance is conventionally indicated for these pregnancies.

Two-hundred and forty (240) women were randomized to domiciliary monitoring
and 175 to in-hospital monitoring. Domiciliary monitoring consisted of daily monitoring of the maternal condition (bloodpressure, temperature, laboratory tests) and the fetal condition by antenatal fetal heart rate cardiotocography. Domiciliary monitoring was executed by trained hospital-based midwives. Fetal heart rates were transmitted by modem to the hospital and analyzed using the Oxford Sonicaid System 8000. The recordings were assessed by the obstetrician on call. The maternal condition was evaluated daily at home by a midwife. A midwife could be reached by telephone for questions as part of the domiciliary monitoring program (24 hours per day). Domiciliary monitored women visited the antenatal clinic once a week for a routine antenatal visit at their obstetrician. Women who had been allocated to in-hospital monitoring were hospitalized and received care according to conventional treatment guidelines. Regardless of monitoring location, all women should deliver in the hospital.

Primary outcome measures were perinatal morbidity, maternal satisfaction, and cost effectiveness. Table 2 shows the obstetric and neonatal outcomes. In the home monitoring group, more infants were born with a 5 minute Apgar score ≤ 7 compared to the hospital group (p=0.04). Fetal distress (5 minute Apgar score ≤ 7 and/or arterial cord pH < 7.10) did not differ significantly between the groups (9.2% in the home monitoring group vs. 12% in the hospital monitoring group). Therefore, the significant difference in Apgar scores is probably without clinical relevance. The Griffith developmental scores performed at the corrected postnatal age of 3 and 6 months did not show significant differences.

Maternal satisfaction, assessed by a written questionnaire, was recorded during antenatal monitoring and at 6 weeks after the delivery. During monitoring, women in the domiciliary group experienced significantly superior 'medical support' (i.e. attitude, contact, and availability of the formal caregivers at home or in the hospital, and the time, attention, practical and emotional support they deliver to the pregnant woman). Moreover, women in the domiciliary group perceived significantly less burden for themselves and their partners compared to the women in the in-hospital monitoring group. Partners' opinions and experiences have not been assessed directly. During antenatal monitoring, women in both groups felt equally safe.

Women in the in-hospital monitoring group on average spent 13.3 days in antenatal care. Women in the domiciliary group on average spent 15.6 days in antenatal care (13.3 days vs. 15.6 days, p=0.046), of which 20.2% in the hospital and 79.8% at home. Eighty-four women in the in-hospital group and 57 women in the domiciliary group were antenatally discharged (84/175 [48.0%] vs. 57/240 [23.8%], p < 0.001). If domiciliary monitoring would be implemented as conventional strategy, 18%-21% of the hospital days could potentially be saved.

Iedema et al. conclude that domiciliary monitoring is a safe alternative for hospital monitoring for a selected group of high-risk pregnant women and costs are lower.

The primary aim of this study was to establish the feasibility and the equivalence of
<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>In-hospital monitoring</th>
<th>Domiciliary monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mothers n=175</td>
<td>Mothers n=240</td>
</tr>
<tr>
<td></td>
<td>Neonates n=195</td>
<td>Neonates n=266</td>
</tr>
<tr>
<td>Gestational age at birth (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 30 weeks</td>
<td>0.6</td>
<td>0.4</td>
</tr>
<tr>
<td>30–&lt; 34 weeks</td>
<td>7.4</td>
<td>6.3</td>
</tr>
<tr>
<td>34–&lt; 37 weeks</td>
<td>17.7</td>
<td>22.5</td>
</tr>
<tr>
<td>37–&lt; 42 weeks</td>
<td>68.6</td>
<td>66.2</td>
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<tr>
<td>≥ 42 weeks</td>
<td>5.7</td>
<td>4.6</td>
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<tr>
<td>Mode of delivery (%)</td>
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<tr>
<td>Spontaneously</td>
<td>58.9</td>
<td>61.7</td>
</tr>
<tr>
<td>Assisted vaginal delivery</td>
<td>14.3</td>
<td>13.8</td>
</tr>
<tr>
<td>Primary cesarean section</td>
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<td>14.2</td>
</tr>
<tr>
<td>Intrapartum cesarean section</td>
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<tr>
<td>Induction of labor</td>
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<td>45.0</td>
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<tr>
<td>Birth weight (%)</td>
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<tr>
<td>&lt; 1500 g</td>
<td>6.2</td>
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<tr>
<td>1500–&lt; 2000 g</td>
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<td>17.9</td>
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<td>≥ 2500 g</td>
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<tr>
<td>5 minute Apgar score (%)</td>
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<td></td>
</tr>
<tr>
<td>≤ 7</td>
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<td>6.8</td>
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<tr>
<td>Arterial cord pH (%)</td>
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<td></td>
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<tr>
<td>&lt; 7.10</td>
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<tr>
<td>≥ 7.10</td>
<td>71.3</td>
<td>71.3</td>
</tr>
<tr>
<td>pH not measured</td>
<td>21.5</td>
<td>21.9</td>
</tr>
<tr>
<td>Neonatal admission (%)**</td>
<td>59.0</td>
<td>62.1</td>
</tr>
<tr>
<td>Perinatal death (n)</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

* There are no significant differences between the in-hospital monitoring group and the domiciliary monitoring group except for the 5 minute Apgar score (p=0.04).

** Admitted to Neonatology Ward or NICU.

Table 2. Obstetric and neonatal outcome of the randomized clinical trial comparing domiciliary monitoring versus in-hospital monitoring conducted at the University Hospital Utrecht*38*

neonatal outcome ('safety'). Besides feasibility and safety, cost-effectiveness and maternal satisfaction were major outcome measures. Based on this study, the Dutch Minister of Health, Welfare and Sports recommended de-institutionalized care for high-
risk pregnant women who have an indication for clinical surveillance. Financial coverage of de-institutionalized obstetric surveillance is currently under consideration.

These studies show that domiciliary antenatal fetal monitoring is feasible in technical and organizational respect. Safety, maternal satisfaction, and family burden have only been established in the Utrecht study. None of the studies has evaluated quality of care. The organization of domiciliary monitoring differs considerably between the studies. The studies are too heterogeneous to make valid comparisons.

1.4.4. Summary

Domiciliary antenatal monitoring has been tried in two categories of patients-conditions. One category consists of uterine activity monitoring of pregnant women with pre-labor preterm rupture of membranes (PPROM) who are at risk for infection and/or preterm birth, and women at risk for (impending) preterm labor. The other category consists of antenatal monitoring of the fetal condition in medium-risk and high-risk pregnant women.

Domiciliary uterine activity monitoring of women with PPROM is feasible and largely acceptable, and hospitalization is reduced or postponed. However, firm evidence on the equivalence of neonatal outcomes ('safety') is absent because of a lack of statistical power. As only few women are eligible for this mode of monitoring, it is uncertain whether the implementation of this mode of monitoring is worthwhile.

Domiciliary uterine activity monitoring of women at risk for preterm labor has been set-up in order to detect preterm labor or preterm birth in an early stage. The premise is that early treatment of preterm labor might contribute to a decrease in neonatal morbidity or mortality. Literature indicates two important findings. Firstly, uterine activity monitoring is not effective in preventing preterm delivery in the groups of women studied. Secondly, the early detection and treatment of preterm labor is questionable as the prevention of preterm delivery using tocolysis beyond 34 weeks of gestational age lacks evidence. In summary, the extension of obstetric care to early detection of preterm labor does not result in improved obstetric outcome.

Based on the currently available evidence, we endorse the 1996 ACOG Committee Opinion that there is no reason to implement home uterine activity monitoring in women with PROM at (high-)risk for preterm labor.112

Domiciliary monitoring has also been investigated in women at medium-risk or high-risk for fetal distress. Domiciliary antenatal fetal monitoring is feasible in technical and organizational respect and largely accepted by the pregnant women. However, there is little evidence on the other aspects associated with domiciliary monitoring. The equivalence of obstetric outcomes has been established convincingly in only one study.138 Two studies indicate that domiciliary fetal monitoring reduces hospital admissions and/or in-hospital stay without having adverse effects on obstetric and neonatal outcome.
There is no firm evidence on the cost-effectiveness and quality of care of these programs. Similarly, no study has formally assessed women's health status or health-related quality of life other than the mode of delivery as a proxy. The inclusion rates suggest that women may largely accept domiciliary monitoring but a formal assessment of women's preferences for domiciliary versus in-hospital monitoring is not available. Evidence on the effects of increased de-institutionalization on satisfaction and women's social environment (family effects, informal caregiving) is only sparsely available.

The majority of studies on domiciliary monitoring have used the 'hospital-based transferred care' or 'outreaching' model: care is provided at home by hospital-based providers who are responsible. Within this model, one option is to implement the actual monitoring as self-monitoring: if the pregnant woman is prepared to take responsibility, she may execute the monitoring herself. Alternatively, monitoring may be performed by a trained nurses or midwives who regularly visit the women at home. Although both models have been tried, a formal comparison of these alternatives is absent.

Continuity of care and concerted action of caregivers in most studies were restricted to hospital-based nurses, midwives and obstetricians. A close collaboration between these professionals is feasible. Only the Gorinchem study has tried an alternative model including general practitioners and district-nurses sharing responsibility with hospital-based nurses and obstetricians. The results of this study are unknown.

1.5. Objectives and outline of the thesis

This thesis offers a comprehensive evaluation of a program on de-institutionalized obstetric care in the Dutch health care system: the introduction of domiciliary antenatal fetal monitoring as compared to conventional in-hospital antenatal fetal monitoring and hospitalization in selected high-risk pregnant women. De-institutionalization in this thesis is defined as the transfer of the setting of health care from highly specialized medical settings to medically less structured settings (see section 1.1).

The following research questions will be answered:

1. Is domiciliary antenatal fetal monitoring feasible?
2. Is domiciliary antenatal fetal monitoring effective?
3. Does domiciliary antenatal fetal monitoring affect continuity of care?
4. Is domiciliary antenatal fetal monitoring efficient? Does it contribute to cost containment?
5. Does domiciliary antenatal fetal monitoring allow the individualization of care? What is the balance of individualization as viewed from the woman's perspective and societal efficiency?
We discuss the contribution of domiciliary antenatal fetal monitoring to (de)medicalization and address the implementation of domiciliary antenatal fetal monitoring in Dutch obstetric care.

In Chapter 2, the feasibility and safety of domiciliary antenatal fetal monitoring as compared to conventional in-hospital monitoring in a selected group of high-risk pregnant women are assessed in a randomized controlled trial. Safety is evaluated in terms of neonatal health outcomes. Primary outcome measures are neonatal mortality and Prechtl's neurologic optimality score as a proxy of neonatal health status.

The inter-observer variation of Prechtl scores, and thereby the validity of the main result of the trial, is evaluated in Chapter 3.

After the assessment of neonatal health outcome (Chapter 2), maternal health outcome is evaluated in Chapter 4. Maternal health status is measured as generic health-related quality of life (RAND SF36-Dutch version) and social support (Social Experiences Questionnaire) at two moments in time: antenatally at study entry and at 6 to 8 weeks after the delivery.

In Chapter 5, the economic efficiency of a domiciliary antenatal fetal monitoring program is evaluated using a conventional cost-effectiveness analysis with conventional in-hospital monitoring as the reference strategy.

Domiciliary and in-hospital monitoring might also affect the social environment of the pregnant woman. In Chapter 6, the effects of antenatal fetal monitoring on 'others than the patients' are evaluated in terms of 'family burden'.

In Chapter 7, the room for individualization of care – a characteristic of de-institutionalized care – is evaluated by measuring women's strength of preference for domiciliary and in-hospital monitoring, respectively.

Chapter 8 displays a theoretical framework to evaluate the non-health related outcomes or 'process utilities' when health care is provided. In addition, several options are discussed on how to integrate the process utilities in cost-effectiveness analysis.

Based on the framework displayed in Chapter 8, the measurement of 'non-health' outcomes ('process utilities') is applied to the comparison of in-hospital versus domiciliary monitoring in Chapter 9. The 'non-health' outcomes of each monitoring modality are measured using a willingness-to-pay approach.

An alternative approach to the measurement of 'non-health' outcomes is shown in Chapter 10. The 'non-health' related outcomes incorporated in domiciliary and in-hospital monitoring are weighted against a health-related outcome (in our case adverse neonatal outcome) in a trade-off procedure.

This thesis concludes with Chapter 11, in which our findings are summarized and discussed, with specific attention to the methodological considerations and the opportunities for implementation. Suggestions for future research are presented.
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