BMJ Open Protection of pregnant women at work in Switzerland: practices, obstacles and resources. A mixed-methods study protocol

Peggy Krief,^{1,2} Alessia Zellweger,^{1,2,3} Maria-Pia Politis Mercier,³ Brigitta Danuser,^{1,2} Pascal Wild,^{1,2,4} Michela Zenoni,^{1,2} Isabelle Probst³

ABSTRACT

Introduction Like most industrialised countries, Switzerland has introduced legislation to protect the health of pregnant workers and their unborn children from workplace exposure. This legislation provides for a risk assessment, adaptations to workplaces and, if the danger is not eliminated, preventive leave (prescribed by a gynaecologist). This study's first objective is to analyse the degree to which companies, gynaecologists and midwives implement the law. Its second objective is to understand the obstacles and resources of this implementation, with a focus on how relevant stakeholders perceive protective measures and their involvement with them.

Methods and analysis Data will be collected using mixed methods: (1) online questionnaires for gynaecologists and midwives; telephone questionnaires with company human resources (HR) managers in the healthcare and food production sectors; (2a) case studies of 6–8 companies in each sector, including interviews with stakeholders such as women workers, HR managers and occupational health physicians; (2b) two focus groups, one involving occupational physicians and hygienists, one involving labour inspectors. Quantitative data will be analysed statistically using STATA software V.15. Qualitative data will be transcribed and thematically analysed using MaxQDA software.

Ethics and dissemination The Human Research Ethics Committee of the Canton Vaud (CER-VD) has certified that this research study protocol falls outside of the field of application of the Swiss Federal Act on Research Involving Humans. The publications and recommendations resulting from this study will form the starting point for future improvements to the protection of pregnant women at work and their unborn children. This study started in February 2017 and will continue until January 2020.

INTRODUCTION

In Switzerland, as in the rest of the world, women represent a considerable proportion of the working population (46% in 2016, Swiss Federal Statistical Office). At 82.2%, the country's proportion of women aged 25–54 years and in paid employment is one of the highest in Europe.¹ Reconciling pregnancy and work

Strengths and limitations of this study

- A mixed-methods study provides insights into the underlying mechanisms of the implementation of maternity protection legislation.
- The experiences of multiple relevant stakeholders (gynaecologists, midwives, occupational physicians and hygienists, work inspectors, company representatives and women workers) will be taken into account.
- The study is limited to the French-speaking part of Switzerland, and the case studies include only two business sectors, such that results cannot be generalised to the overall situation in Switzerland.
- Certain categories of workers will not be interviewed, notably, temporary staff and women who left the company after giving birth.

is, therefore, more than merely a medical issue; it is an important economic challenge, too. Overall, the international medical literature shows that work in itself does not pose a risk to pregnancy.²⁻⁴ Nevertheless, certain specific professional activities^{2 5-9} can represent a risk to pregnancy and the unborn child, and these justify the introduction of legal provisions for the protection of maternity at work.¹⁰ Respecting those laws is of crucial importance to perinatal health. The maternity protection legislation (MPL) in place in most industrialised countries¹⁰ requires that occupational risks to pregnancy are assessed and measures are taken to avoid exposing pregnant workers to risks. This should primarily be done by eliminating those risks or adapting working conditions. If those options prove infeasible, employees should be transferred to another post or, as a last resort, granted paid leave.

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¹Occupational Health, Institute for Work and Health (IST), Lausanne, Switzerland ²University of Lausanne and Geneva, Switzerland ³School of Health Sciences (HESAV), University of Applied Sciences and Arts Western Switzerland (HES-SO), Lausanne, Switzerland ⁴Scientific Management, INRS, Vandœuvre-lès-Nancy, France

Correspondence to Dr Peggy Krief; peggy.krief@chuv.ch Work (OProMa) set out which types of jobs are considered dangerous or arduous, the processes to be put in place to counter the risks and the responsibilities of all the actors involved.¹¹

Employers are obliged to have an authorised specialist carry out an analysis of workstation risks before hiring women. This risk analysis must be communicated to the female employee and her immediate work supervisors.

Occupational physicians and hygienists or other authorised occupational health specialists must carry out risk analyses in order to minimise professional exposure to dangers via adaptations to workstations or changing job tasks. Those occupational health professionals then advise women workers, employers and other healthcare professionals.

It is the role of the treating physician (usually gynaecologist/obstetricians) to verify whether their patients are exposed to any professional activities banned under the OProMa. If they are, the risk analyses must be transferred to a doctor for a decision on whether the expectant mothers can safely continue employment at their workstations. In the absence of a risk analysis, but in the presence of presumed dangers, the doctor will issue a medical certificate of incapacity (preventive leave) according to the precautionary principle. Preventive leave is financed by employers until they remedy the dangerous situation in the workplace. The medical certificate of incapacity is different from sick leave, which is financed either directly by the employer or by the employer's loss of income insurance.¹²

Establishing a disparity between legislative provisions and the reality in the workplace

International literature,¹³⁻¹⁶ exploratory studies in Switzerland¹⁷ and the project authors' personal experiences¹⁸ have highlighted several deficiencies in the implementation of the country's MPL: (1) stakeholders' lack of understanding about the risks and the legal provisions in place (employers, gynaecologists and, especially, expectant mothers); (2) cases where neither risk analyses nor workstation adaptations are made; and (3) the use of sick leave certificates in place than preventive leave. The latter practice weakens the law as an incentive for companies to develop internal preventive strategies. Similar findings were also highlighted by the authors in a recent international literature review,¹⁹ inspired by Bronfenbrenner's ecological model²⁰ and realist approaches,²¹ which revealed the many levels of difficulty and complexity in introducing MPL: (1) the lack of knowledge about the legal provisions concerning occupational maternity protection, on the part of employees as well as employers, can have an impact on the implementation of appropriate measures; (2) at the organisational and social levels, the company's status, the collaboration between the different stakeholders and the way in which the notion of risk is defined within a company also play a role; and (3) at the societal level, the implementation of MPL depends largely on political incentives, the standing which women

have in their company and knowledge about professional risks.

Thus, we hypothesised that the difficulties inherent in applying MPL were not only the result of women workers', employers' and healthcare professionals' lack of information, but we also supposed that these difficulties were linked to the complex and partially contradictory requirements of reconciling work and maternity,²² which encourage different actors to develop practices outside of the existing legal framework.

METHODS AND ANALYSIS Study aims

This project aims to understand how MPL is applied within French-speaking Switzerland's companies and the components of its healthcare system and how it is perceived by the stakeholders concerned, particularly pregnant women. By identifying the obstacles and resources of current instruments and practices, the study will form a starting point for work to improve the health protection of pregnant workers and their unborn children. The research questions which will guide the present project are shown in table 1.

Study design

Choice of study design

With a view to getting the best overall picture of the situation, we plan to mix quantitative and qualitative approaches.

The quantitative part's goal is to evaluate the extent to which MPL is applied and to identify the principal factors which impede or facilitate the implementation of its measures. Questionnaires will be sent to companies in the healthcare and food industry sectors and to healthcare professionals in French-speaking Switzerland.

The qualitative part's goal is to understand the means by which different actors appropriate or translate the provisions of MPL and the reasons why companies act the way they do with regard to maternity. Case studies will be made of 6–8 companies per sector, including qualitative interviews with diverse stakeholders and, notably, human resources (HR) managers, occupational health and safety specialists and women workers (approximately 50 interviews in total). Two focus groups will be organised, one with occupational health professionals (occupational physicians and hygienists) and another with work inspectors.

The mixed methods design is the result of the current state of knowledge on this subject: the absence of data on the implementation of MPL makes it necessary to establish the law's current usage and identify the factors underlying the implementation of MPL, using questionnaires, whereas the case studies and focus groups are needed to understand the reasons at the origins of current company practices as well as different actors' representations. The combination and integration of both parts of the study will help us to understand how complex the implementation

Table 1 Data collection methods per research question	er research question			
0	Specific research question	Participants providing data	Data source	Data analysis
1. To what extent is MPL applied within French-speaking Switzerland's companies and the components of its healthcare system?	To what extent is MPL applied by the companies HR managers, employers in the healthcare and food industry sectors? To what extent is MPL applied by gynaecologist- Gynaecologist-obstetricians and obstetricians and midwives?	HR managers, employers Gynaecologist-obstetricians and midwives	Telephone questionnaires Online questionnaires	Descriptive analyses using STATA Descriptive analyses and hierarchical cluster analyses using STATA
 What are the factors influencing the implementation of MPL within French-speaking Switzerland's companies and the components of its healthcare system? 	What are the principal difficulties in the implementation of MPL in companies in the healthcare and food industry sectors? What are the principal difficulties in the implementation of MPL by gynaecologist- obstetricians and midwives?	HR managers, employers Gynaecologist-obstetricians and midwives	Telephone questionnaires Online questionnaires	Descriptive analyses using STATA Descriptive analyses and hierarchical cluster analyses using STATA
 How is MPL translated into concrete measures within companies? 	What are the disparities between the legal framework, the preventive measures planned by companies and the reality in the workplace? What are the obstacles and aids to the implementation of MPL?	HR managers, employers, heads of department, occupational physicians and hygienists, women workers who have been pregnant in the last five years	Semi-structured qualitative interviews	Thematic analysis of content
 What is the experience of the actors concerned, particularly pregnant workers, with regard to the implementation (or not) of maternity protection measures? 	What is the impact on women's real-life experiences with regard to reconciling work and maternity? What is their experience of the adequacy of maternity protection measures with regard to their own needs?	Women workers who have been pregnant in the last 5 years.	Semi-structured qualitative interviews	Thematic analysis of content
 How do occupational physicians and hygienists and work inspectors perceive MPL? 	What is their opinion about current maternity protection measures? How would they propose to improve MPL and its implementation?	Occupational physicians and hygienists and labour inspectors	Focus groups	Thematic analysis of content
HR, human resources; MPL, maternity protection legislation.	stection legislation.			

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of these legal protection measures is, as well as what the current problematic aspects of the provisions are. 23

Field of study

This study only has the means to look at Switzerland's six French-speaking cantons. With regard to the companies involved, the quantitative and qualitative parts of the study will also have to be restricted to the food industry and healthcare sectors (respectively, divisions 10 and 86 of the General Classification of Economic Activities (NOGA), Swiss Federal Statistical Office). These two sectors were selected in order to focus solely on activities where pregnant workers are especially at risk and therefore require the implementation of MPL. Furthermore, they employ a large number of female workers, which allows us to acquire a realistic sample for a telephone survey. This selection also provides to receive the support of the employers' associations concerned so as to encourage a good reception for the questionnaire and the company case studies (feasibility). The two sectors were chosen because they can involve exposure to factors, which are a risk to maternity, and they employ significant numbers of women. In Switzerland in 2015, women made up 44.3% of the workforce in the food industry (NOGA 10) and 76.4% in the healthcare sector (NOGA 86).²⁴ They were also chosen because of their economic differences (industrial vs service sector; uniquely private vs partially public), the types of jobs involved (manual or technical work in the food industry vs a wide range of healthcare jobs) and the sociodemographic profiles of the employees.

Quantitative methodology

Sample selection and data collection

The questionnaire for companies will be carried out by telephone on a sample of 200 companies distinguished by economic sector and size. The sample will be chosen at random from the Business and Enterprise Register by the Swiss Federal Statistical Office. An appointment will be made with a competent person within the organisation to answer the questionnaire. This telephone interview should be completed within 20 min. The expected success rate for this operation is 25%, which implies that the initial sample will have to comprise 800 companies.

The questionnaire for gynaecologist-obstetricians and midwives will be sent out via email to all of Frenchspeaking Switzerland's specialist gynaecologists-obstetricians, to doctors undergoing their specialisation and to members of the Swiss Federation of Midwives (FSSF), whether they work in hospital environments or private practice. Around 400 specialists (Swiss Medical Association statistics, 2013) will be contacted via the Swiss Gynaecology and Obstetrics Association and its cantonal chapters; around 600 midwives (FSSF statistics, 2013) will be contacted via the FSSF. The expected response rate of gynaecologists and midwives is around 30%. Although midwives are not included in the OProMa, it is essential to involve them in the study because they carry out many maternity-related consultations, notably in maternity Online questionnaires have been selected because, in the investigators' experience, healthcare professionals are more likely to respond to online questionnaires they find in the email inboxes. This is different with companies, however. The telephone survey will allow us to get a better rate and more accuracy than a written questionnaire.

Questionnaires

The questionnaires include 31 questions for physicians and 30 for midwives, with 31 in the questionnaire for companies. The questions have been designed based on national and international literature and on the expertise of the project's research team. A test phase is planned for all three questionnaires.

Data collection

Questions for all the questionnaires were generated using Sphinx online software (V.4.8).

Statistical analyses

Data from the questionnaires' responses will be extracted into an Excel spreadsheet format and will be treated using STATA V.14 software.

Statistical analysis of the responses to the questionnaires from healthcare professionals will involve several stages:

- ► Simple descriptive and correlational statistics on all the items recovered, including associations, will be tested using Fisher's exact test.
- ► Multivariate and hierarchical cluster analyses. This analysis aims to generate hierarchical clusters (or typologies), from the variables describing healthcare professionals' practices on the one hand and from the variables describing their attitudes vis-à-vis legal provisions on the other. The objective is to identify the typologies of practice and attitudes by grouping together subjects who gave similar responses.
- Association between clusters (or typologies) of practice and attitudes: is one type of attitude associated with a particular type of practice?

With regard to the data from the questionnaires answered by company representatives, the statistical analysis will proceed as follows:

- ► Simple descriptive and correlational statistics on all the items recovered, including associations, will be tested using Fisher's exact test.
- ► For the questionnaires aimed at companies, all the analyses will take into account the initial stratification—food industry and healthcare sector—and will enable an estimation (using survey methods) of the number of women from these two economic sectors for whom MPL is not applied.

Statistical power

For the questionnaire answered by companies, we target an effective sample group of 200 companies. This sample size will enable us to show a 15% difference in the implementation of MPL between the two groups, with a statistical power of 80% at the standard statistical significance threshold of p=0.05.

Because the whole population of relevant healthcare professionals will be targeted and sent the questionnaire, this criterion is not relevant.

Qualitative methodology

We will integrate theory of activity approaches, as developed in the fields of sociocultural psychology^{25–26} and ergonomics,²⁷ in order to make a fine-grained analysis of actors' practices. We always consider maternity protection to be more than the mere implementation of the relevant legal provisions and the resulting application of certain safety measures; rather, maternity protection should always be the result of the contextualised and collective action of all the actors concerned. This activity or action may imply a reconfiguration or translation of the planned measures in function of the perceived challenges, the constraints encountered and the available resources, and also of the dynamics emerging from the interactions in the workplace.²⁸

Case studies

Domains

Case studies will be made on 6–8 different-sized companies from each of the two industrial sectors chosen for the project: healthcare and the food industry. Table 2 shows the number of companies that have been selected for the case studies.

In order to find case study participants, we will ask each company contacted and asked to complete a questionnaire, whether they would agree to take part in the qualitative part of the study.

Data

Data will be collected from the semistructured qualitative interviews with the principal actors involved in maternity protection in participating companies: (1) workers who have been pregnant at work within the last 5 years; (2) HR managers, employers and heads of department; (3) occupational physicians or occupational safety specialists; (4) other actors in the company who are involved in the implementation of MPL (eg, occupational health nurses, social workers, staff or union representatives). Table 3

Table 2 Selection of companies for case studies			
	Small (<50 FTP)	Medium (50–250 FTP)	Large (>250 FTP)
Healthcare	1	one or 2	1
Food industry	1	one or 2	1

FTP, full-time employees.

Table 3 Number of interviews involved in each case study

Number of interviews per company (according to size)	Total estimated for the 6–8 companies
1–6	30–35
1	6–8
1	6–8
0 or 1	4–5
	46–56
	interviews per company (according to size) 1–6 1 1

HR, human resources.

resumes the number of interviews involved in each case study.

Interview contents

Interviews will last between 45 min and 1 hour. Six exploratory interviews have been carried out with workers who had once been employed during their pregnancies.

Table 4 describes the principal contents which will be covered with the different actors during the interviews.

Focus groups

Domains

In order to get expert opinions, we will organise focus group sessions with occupational health professionals (occupational physicians and hygienists) and work inspectors. These professionals were chosen because of their central role in the protection of health at work. The two focus groups will each be made up of 7–8 participants.

Focus group contents

Focus groups will last about 2 hours. Discussions between the participants will be sparked by the findings from the quantitative part of the study as well as questions examining participants' experience and their proposals for promoting maternity protection.

Thematic analysis of the interviews and focus groups

Interviews and focus groups will be respectively audio and video recorded, and their transcripts will be written out verbatim. In transcripts, participants' names will be substituted with a pseudonym, and any personal references which might enable identification of one of the participants will be erased. A thematic analysis will be undertaken to identify all the key categories and themes which emerge from the interviews. Segments of discourse will be coded using MaxQDA software in order to systematically treat passages referring to different themes.²⁹ Any inter-rater disagreement as to which codes should be applied to which segments will be resolved by consensus among the research team. This activity is, therefore,

Table 4 Principal themes to be brought up with the different actors		
Actors	Operationalisation	
HR managers, employers, heads of department	 Number and categories of workers concerned by MPL in the past 5 years. Types of risks or dangerous activities encountered by pregnant employees. Information given to the employee. Measures put in place to encourage the employee to announce her pregnancy. Risk analyses and measures put in place following an employee's announcement of her pregnancy (workplace adaptations, changing job tasks). Collaboration with other professionals. Difficulties met and resources available. Incorporation into company policies and links to health protection in general. Propositions and perspectives. 	
Women workers who have been pregnant in the company in the last 5 years.	 The woman's experience with regard to her pregnancy in an occupational setting (start of pregnancy, announcement to superiors, etc). Information received on MPL. Perception of the risk linked to work or arduous tasks. Adaptations put in place by the company and the perceived level of adequacy with the woman's needs. Difficulties encountered in the protection of maternity in relation to work organisation, working relationships, the job itself, etc. Reduced working hours or exclusion from work. Adaptations put in place by the woman. Propositions and perspectives. 	

HR, human resources; MPL, maternity protection legislation.

a co-construction of knowledge, whose goal is to help knowledge from these different domains emerge using an inductive approach.²⁹

Patients and public involvement

Patients will not be involved in the study. If desired, the results of the study will be forwarded to the participants.

Steering committee

A steering committee will be made up of a dozen representatives from among the actors most concerned by maternity protection. The committee will meet every year throughout the project in order to facilitate investigations in the field, discuss results, sketch out recommendations and encourage the dissemination and use of the results.

ETHICS AND DISSEMINATION

Ethical and safety considerations

The Human Research Ethics Committee of the Canton Vaud (CER-VD) has certified that this research study protocol falls outside of the field of application of the Swiss Federal Act on Research Involving Humans because it will not collect 'personal health data'. The research team members have made sure that the study respects the following ethical principles: all the personal data gathered will be treated confidentially; questionnaire, interview and focus group participants will be anonymised; written informed consent will be requested from all the interview and focus group participants; data will be securely stored; and the data will only be used for research purposes. Participation in this research study will be voluntary. In the hypothetical case where, during an interview, an employee reveals the existence of a working environment which might be dangerous for her health or that of her colleagues, the research team will suggest that she contacts the Institute for Work and Health.

Data privacy will be guaranteed: all the research data gathered during the project will be treated confidentially; non-anonymised data will be kept under lock and key (video and audio recordings, written informed consent forms and questionnaires, coding lists); anonymisation of interview transcripts (names and companies); persons interviewed and companies will be identified using pseudonyms; and communications and publications will not enable identification of individuals or companies.

With a view to equity, the case studies will cover unskilled workers, short fixed-term contract or casual workers, and workers from disadvantaged social groups. These types of employees are more often subject to harmful working conditions³⁰ and are frequently under-represented in surveys. We will thus notably attempt to include non-Francophone workers by offering translation. Temporary staff and women who have since left participating companies will not be interviewed. These two categories of workers are, however, more likely to experience difficulties than full-time employees. The analysis of the case studies will take these limitations into account.

Dissemination

Articles

We plan to publish 4–5 main articles in peer-reviewed scientific journals; we will also publish several articles in professional journals, and we will communicate our results in congresses covering a variety of disciplines.

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This significant research project will also result in a PhD thesis.

Training

Because the research team is directly involved in training gynaecologists, midwives, occupational physicians and occupational health nurses, the project's conclusions will be directly transferable to teaching (implementation of the legal provisions on maternity protection, the consideration of work-related issues and the dispensation of relevant advice during pregnancy monitoring). At the end of the research project, a day's training workshop will be organised for professionals and institutions involved in the field of maternal health, to both disseminate results and debate possible improvements to maternity protection and the legislation covering it.

Recommendations

This project will enable the design of recommendations to raise the awareness of all the stakeholders in the field of maternity protection (including the general public and the public authorities) about the occupational risks to maternity and the need to improve preventive measure in this area.

By objectifying the degree of implementation of the legal provisions on maternity protection, as well as their deficiencies, this project will encourage a revision of the relative legal instruments and the design of new strategies by organisations which have to execute them. This will optimise the implementation of legal provisions and ensure greater maternity protection at work across Switzerland.

The project could also bring into question the current attribution of roles made by the OProMa. For example, this could be by entrusting the job of giving an opinion on a pregnant employee's aptitude or inaptitude to work to occupational physicians because of their specialist training which is at the interface between the worlds of work and health. It could also be by taking into account the fact that some pregnancies are only ever monitored by midwives.

Perspectives

Thanks to its combination of sources of information, from companies, workers and healthcare professionals, this research project will provide objective data that have never before been gathered on the implementation of MPL in Switzerland. This will also enable comparisons with the policies in other countries. The project's quantitative and qualitative mixed-methods design aims to provide a significant contribution to our knowledge about maternal health protection in Switzerland in the face of occupational risks. Indeed, previous research has repeatedly shown the gaps between recommended levels of protection for workers and those which are in fact implemented in occupational settings. There is consequently a need to understand the reasons and determining factors for actors' practices in particular occupational situations,^{26 31–33} in this case, maternity.

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Competing interests None declared.

Patient consent Not required.

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Data sharing statement Questionnaires and interview guides are available on request.

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