

EU Optimal Blood Use Project

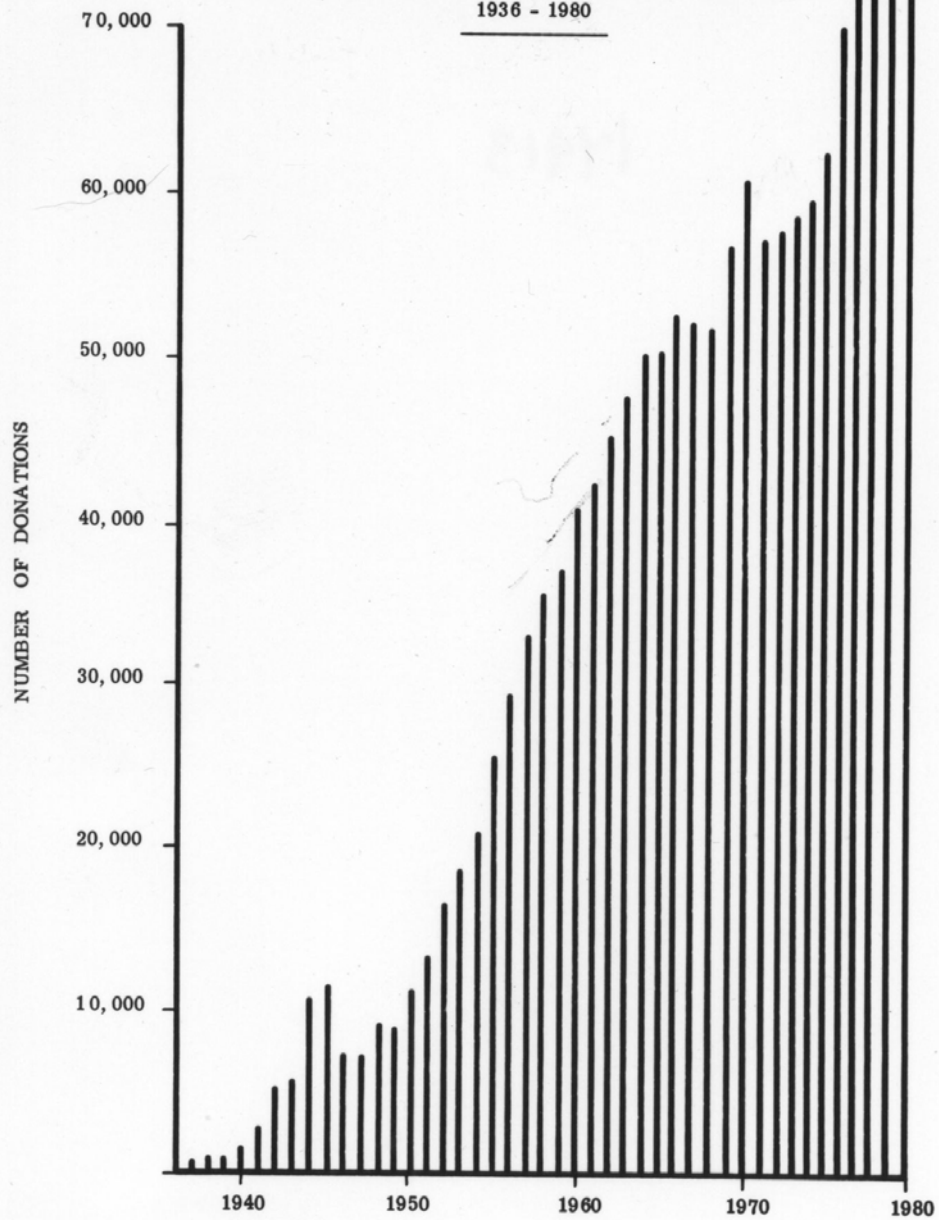
Why and how it began

Brian McClelland

"Optimal Blood Use - Inspection of Blood
Establishments and Hospital Blood Banks" Madrid
October 4th, 2011

S. E. SCOTLAND
ANNUAL BLOOD DONATIONS COLLECTED

1936 - 1980



1982: Survey of practice

- Just before AIDS
- All surgeons and anaesthetists in our region (1.2 million population)
- Knowledge, attitudes and practice examined in a structured interview conducted by an anaesthetist
- Most believed in 100 g/l minimum Hb level

**There was – and still is - much
uncertainty about when to transfuse
red cells**

“The aetiology of the requirement that a patient must have 10 gm of Hb prior to receiving an anaesthetic is cloaked in tradition, shrouded in obscurity and unsubstantiated by clinical or experimental evidence. Until recently it has remained a standard of anaesthetic practice”

1988

Zauder, NIH Red Cell Consensus conference

2009

Lower Hb (~7g) vs Higher Hb (~10g) in critical illness the evidence from randomised trials

- Premature babies and small children:
 - No difference
- Adults
 - Lower Hb possibly better in fitter patients
 - Higher Hb possibly better in cardiac patients
- Does this mean
 - No adverse effects of red cell transfusion?
 - Lower Hb not harmful?

SO....

**why did we start to work on
improving clinical
transfusion practice ?**

1980

- Increasing use of red cell transfusion
- Uncertainty about the clinical benefits in many cases
- Lots of beliefs and opinions
- Very little evidence to guide clinicians

1970-1991

Old risks recognised and characterised

Hepatitis – non A non B

Slow realisation that it can be serious

Patients harmed by mistakes in *transfusing*

McClelland and Philips 1994 Brit Med J

Serious Hazards of Transfusion (UK)

International Haemovigilance network

New risks appearing

1982 AIDS

1989 hepatitis C

2001 variant CJD

Safe and effective blood components

**Safely and effectively transfused
patients**

Some steps on the way

1994 Safe and Effective use of blood in surgery
(SANGUIS)

1995 Optimal Use of Donor Blood
Report to Scottish Health Department

2000 ISPOT – International study of
perioperative transfusion



European Commission

DG XII – Science, Research and Development

Safe and Good Use of Blood in Surgery (SANGUIS)

**Use of blood products and artificial
colloids in 43 European hospitals**

Edited by

Girolamo Sirchia

Anna Maria Giovanetti

Brian McClelland

Giovanni Nicola Fracchia



Biomedical and Health Research

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THE SCOTTISH OFFICE
National Health Service in Scotland

OPTIMAL USE OF DONOR BLOOD



Blood transfusion has a high public profile due to concerns about risks of HIV transmission and, more recently, Hepatitis C. There are alternatives to some blood products, suitable for some patients. The evidence about safety and efficacy of both alternatives and blood products is often inadequate. In many clinical cases, a simpler and safer option may be to avoid or reduce the use of blood.

Evidence of very large variations in the use of blood products between clinical centres provides a strong indication that practice is often less than optimal.

Many Scottish clinicians working in specialties where blood products are used are clearly aware of the importance of safe and effective transfusion practice and have contributed to the development of this report.

The mechanisms for improving practice are clearly inadequate. It is evident that existing 'guidelines' for transfusion do not meet today's rigorous standards of validity. To remedy this will take time and investment, and may be impossible in some instances. However, the existing guidelines can have a very useful role if the will and mechanisms are there to implement them.

This is a substantial task and it cannot be divorced from the programmes to implement condition - specific guidelines for patients who may require blood product therapy.

Information for patients and prescribers

1. An authoritative peer-reviewed report should be prepared and published, showing calculations of the best estimates of local risks of transfusion for patients in Scotland, based on the relevant epidemiological data for Scotland.
2. In view of evidence that there are failures to provide patients with basic information (e.g. warning of the probable need for transfusion), there should be local procedures for briefing patients who are likely to be transfused.
3. It is assumed that clinicians have a duty of care to explain to patients the risks of transfusion, responding if required to the patient's need for further information. To discharge this will require an investment in information materials and possibly also in training for clinicians. Medicolegal and ethical advice is needed on the frequency and nature of the risks that should be disclosed, and on the requirement to explain the existence and potential risks of alternatives to allogeneic transfusion, such as no transfusion, autologous transfusion, or use of epoietin where licensed.
4. SNBTS should ensure that there are effective arrangements to provide information directly to clinicians about the range, indications for, and risks of its products, by distribution of the Compendium of Blood Products and Blood Component Information, and annual revisions of it and the Handbook of Transfusion Medicine.
5. Blood product use for each patient should be recorded so that the data are available for regular reporting of local and national usage, related to case load and case mix, for audit purposes. This should be a responsibility of clinical directorates. This is particularly important in areas of high usage such as cardiac surgery. The audit system to be installed in all Scottish cardiac surgery centres may be an appropriate way of achieving this.

Government action 1999

UK Health Departments issued specific guidance on measures to be taken to improve transfusion practice

Safe and effective transfusion study 2000

SNBTS study evaluated the role of the
transfusion nurse specialist in carrying out a
programme of

**quality improvement in clinical
transfusion practice**

Government action 2003

Scottish department of Health provided funds for national programme - “Better Blood Transfusion”

16 hospital transfusion teams

Transfusion practitioner

Lead clinician

Transfusion laboratory scientist

Acquire and use data – who gets blood and why

**BETTER BLOOD TRANSFUSION PROGRAMME;**

Introduction of tailored information system software to enable the easy collection and analysis of transfusion data for prompt feedback to clinicians and Hospital Transfusion Committees. This would involve the construction of a merged record that is a by-product of routine clinical practice (held on the existing hospital patient administration system) and data extracts from the local hospital laboratory system (and in some cases operating theatre).

Resources developed

E learning system for transfusion

www.learnbloodtransfusion.org.uk

Transfusion information toolkit and guidelines

www.transfusionguidelines.org

National standards for hospital transfusion

<http://www.healthcareimprovementscotland.org>

Database of systematic reviews and clinical trials in transfusion

www.transfusionguidelines.org

Current programme

Education and Training

Clinical Research

Transfusion epidemiology and management
information

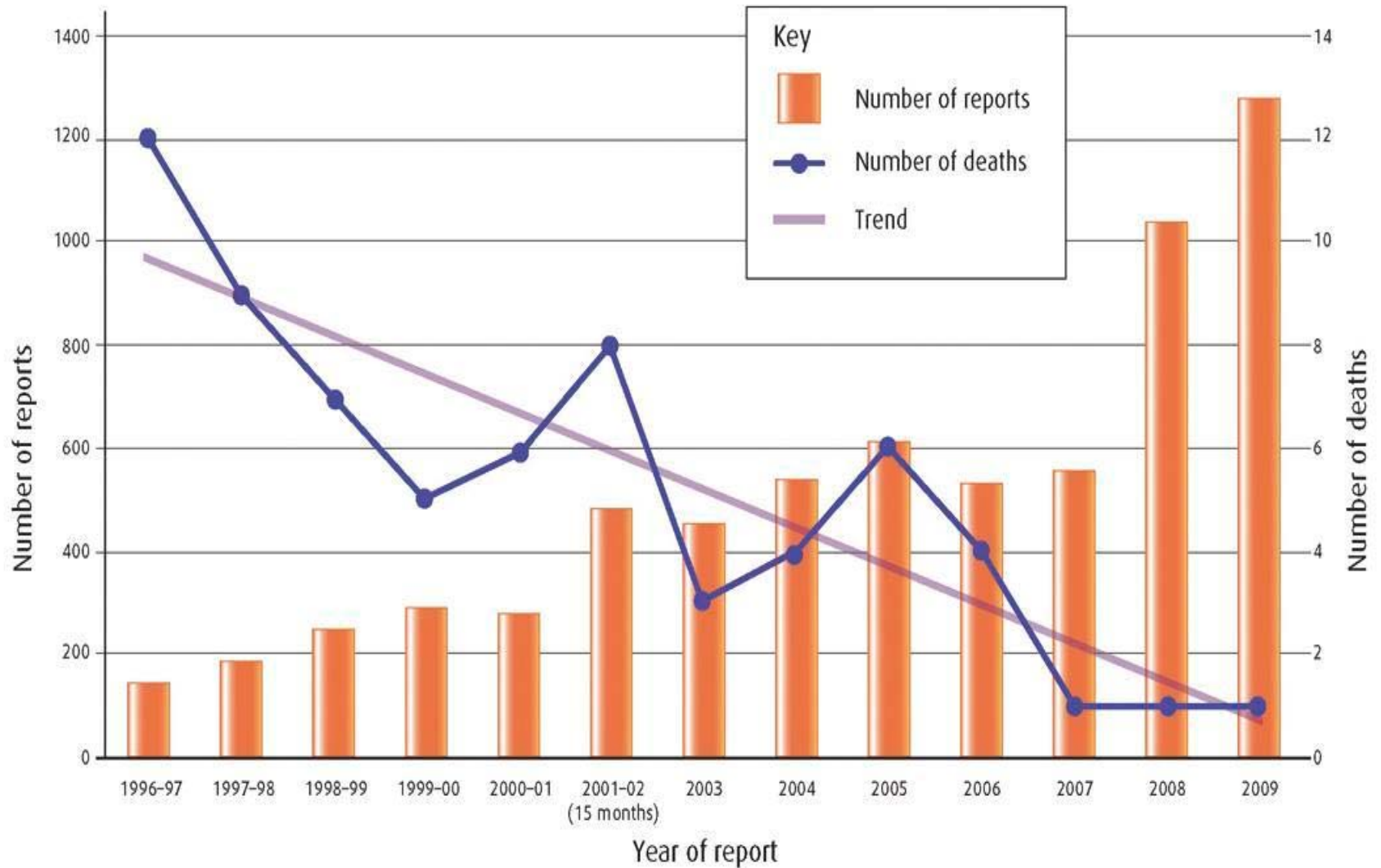
(NHS Scotland Account for blood programme)

Did it make a difference ?

Is transfusion safer for patients

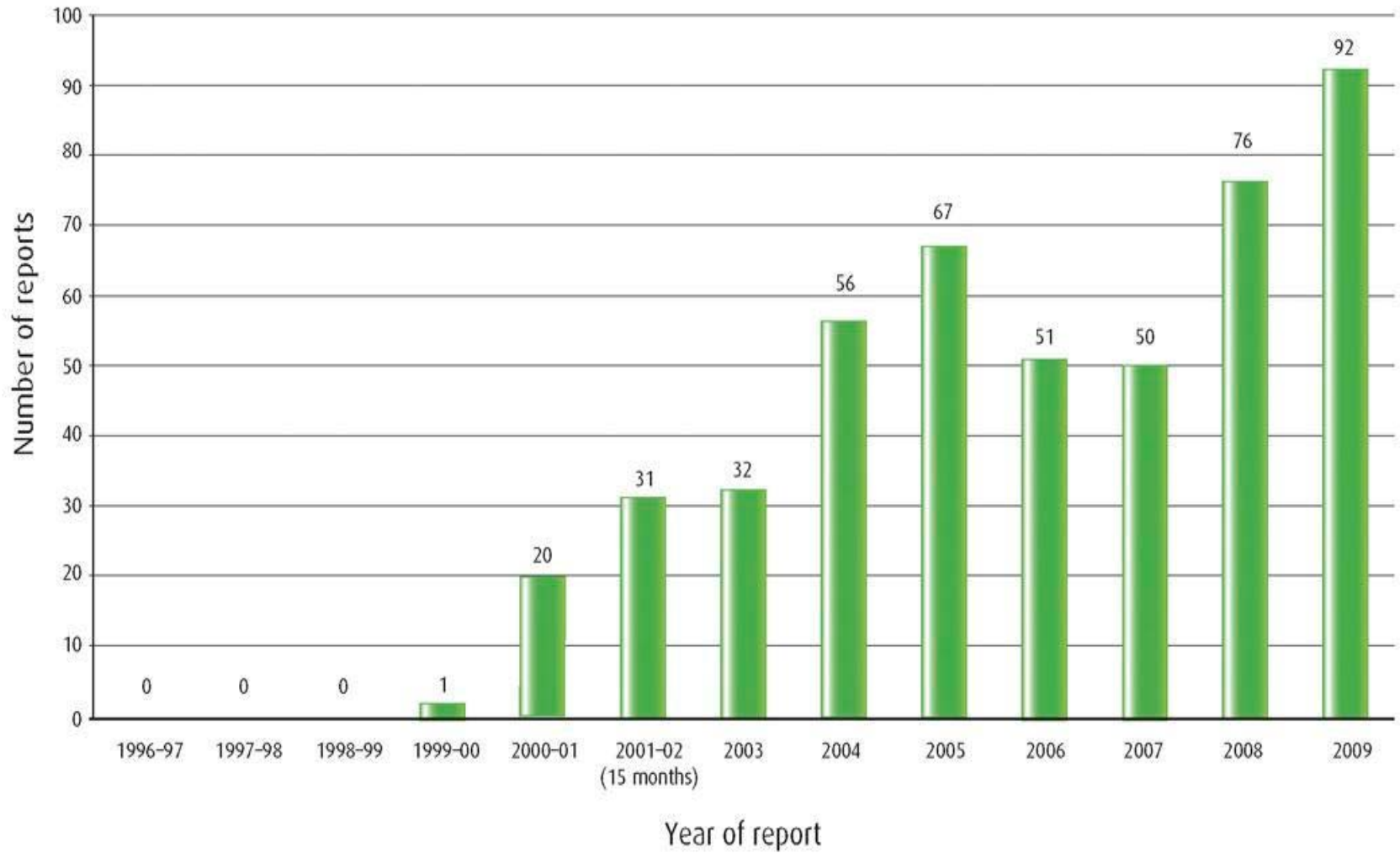
Do we make better use of donated blood ?

Total reports and total deaths definitely due to transfusion 1996 - 2009



SHOT

Cases of inappropriate and unnecessary transfusion 1996 - 2009



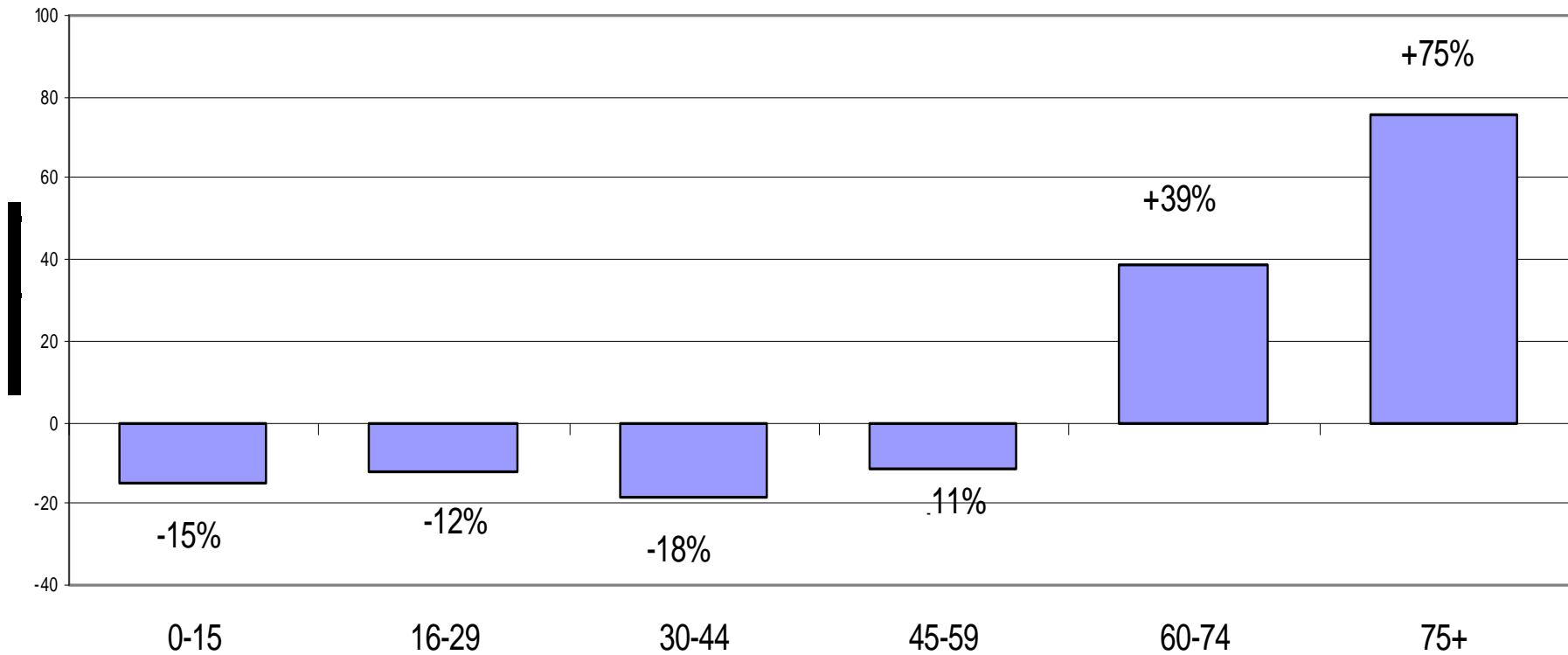
SHOT

Changes in blood units collected Scotland 1999-2010

1	313,000 units
2010	220,000 units

Projected change in age structure

Figure 4 The projected percentage change in age structure of Scotland's population, 2004-2031¹



¹ 2004-based projections

Age

RBC Units Transfused by age band, 2005/06

RBC units transfused per 1,000 population by agegroup
and sex (all Scotland , exluding FV)

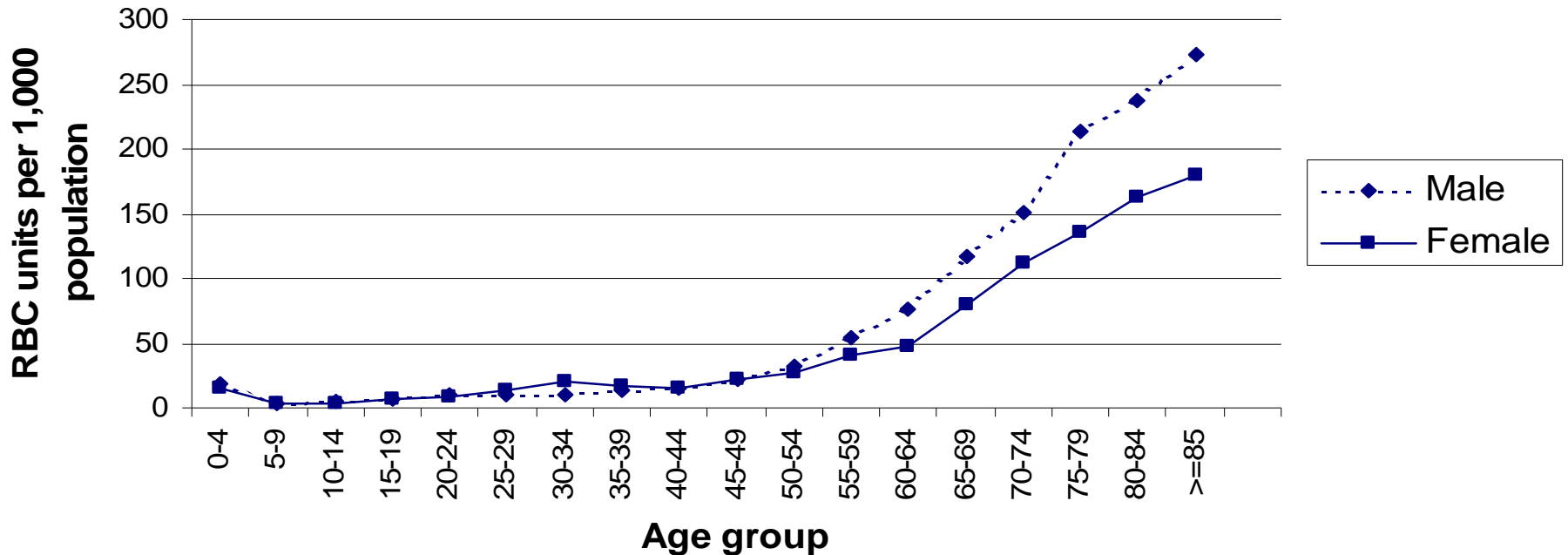
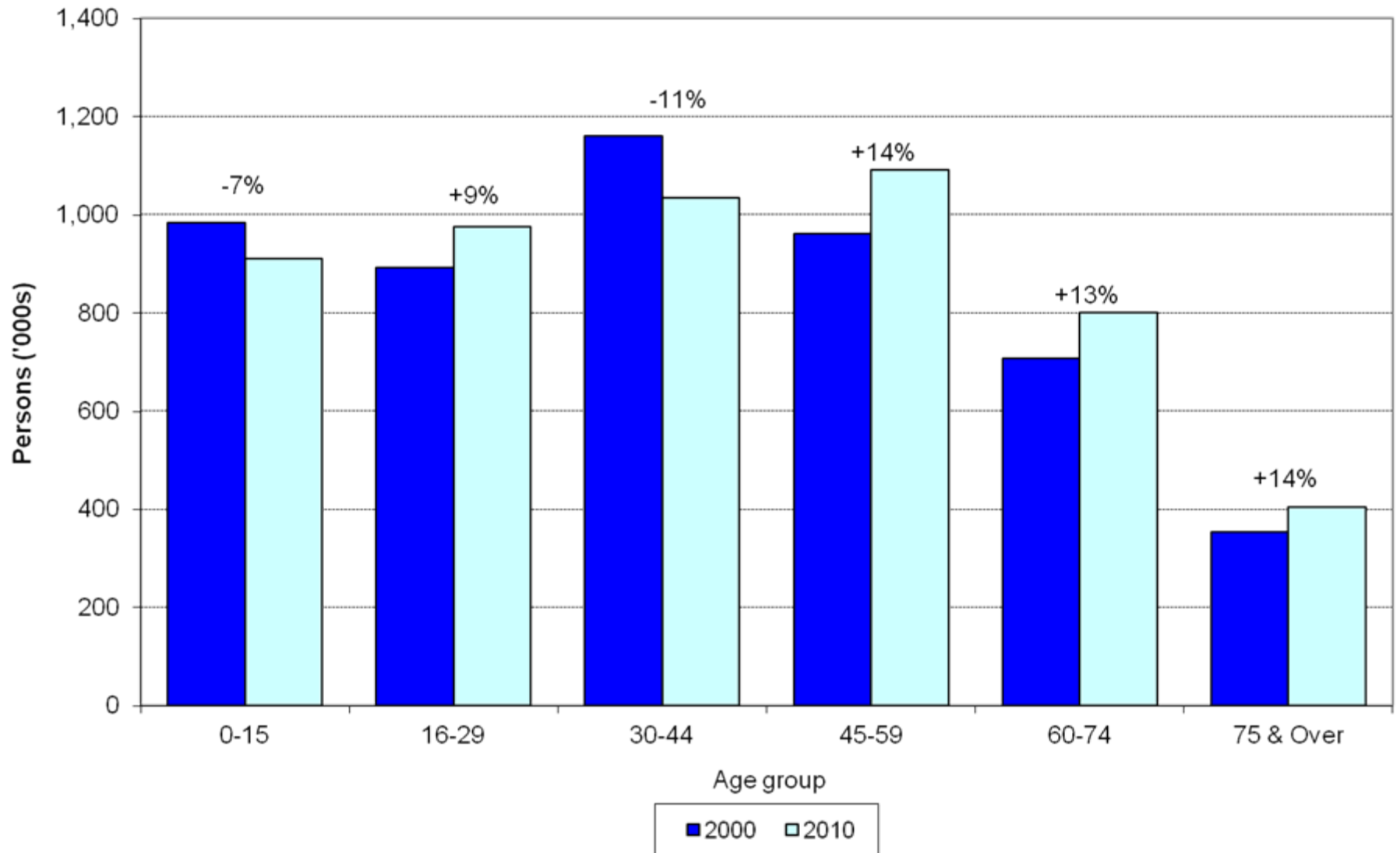
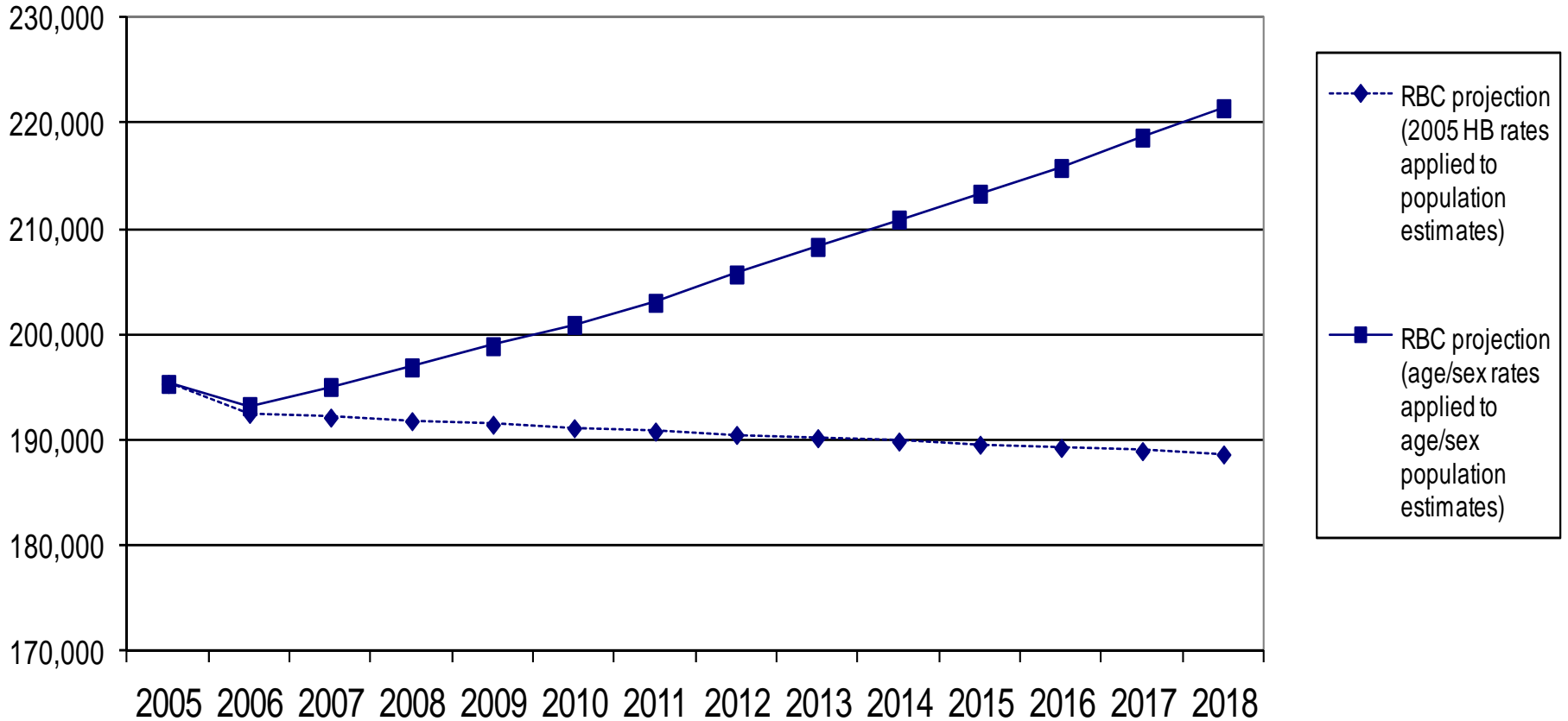


Figure 4 The changing age structure of Scotland's population, 2000-2010



RBC Projections for Scotland (excluding Forth Valley), 2006-2018



What was the EU saying ...?

Wildbad Kreuth Report (EU) 1999

Transfusion of blood ...involves numerous steps ...which need to be strictly controlled to ensure the safety of patients and to prevent (avoidable) adverse events.

The patient, including assessment of physical condition and the need for blood under emergency or non emergency conditions; verification of identity; informed consent to the transfusion and taking a blood sample for pre transfusion testing

The (blood) product, including; reserving products in the transfusion service; identification of the assigned unit; delivery to the clinical ward and management of used and unused blood products

The product and the patient including: identification before transfusion; administration to the patient; documentation of outcomes”

Wildbad Kreuth Report (EU) 1999

“Every effort should be made to establish a quality management system in the clinical part of the blood transfusion chain”

Aims of the Optimal use of Blood Project

To provide PRACTICAL advice and ideas that we hope will be useful to anyone working to make transfusion safer and more clinically effective

To benefit more patients

To harm fewer patients

Scope of the manual

The clinical transfusion process

Transfusion of the

right unit of blood

to the right patient

at the right time, and

in the right condition

Given according to

appropriate guidelines

and sound clinical indications

Quality assurance

means all the activities of the clinical transfusion process that have the object of ensuring that blood and blood components are used optimally

Looked at from the patient's point of view...

Patients' questions – could be your questions

One way to think about what quality management means in clinical transfusion is to consider some questions that you might ask if you were to have a transfusion

Do I really need to have a blood transfusion?

Will it help me?

Could it do me harm?

Will they give me the right blood?

Will I feel unwell during the transfusion?

If I feel bad during the transfusion will someone come to help me?

If I need blood in an emergency will they get it to me in time?

Will someone knowledgeable take the time to explain all this to me?

Is the hospital staff properly trained to give me the transfusion?

How do I know that the hospital does these things well?

With questions like these, the patient is seeking some evidence that the hospital does a good job in providing blood transfusions.

One way that the hospital can reassure is by providing evidence that things are done correctly. This could be information about training, documentation of procedures, or results of checks of performance or comparisons of results between one hospital and others. **All these are parts of a quality system.**

The EU OBUP Manual provides practical guidance that can help to provide answers to questions of this type, whether they are asked by patients or, in different ways, by quality inspectors, auditors or regulators.



Manual of Optimal Blood Use

Safe, clinically effective and efficient use of donated human blood



Optimal Blood Use
Project

**On behalf of
everyone who
worked on the
project...**

**We hope you find it
useful!**